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# Nová cílená léčba pro ankylozující spondylitidu – upadacitinib: studie SELECT AXIS I

prof. MUDr. Karel Pavelka, DrSc. Revmatologický ústav, Praha

- 1 Sieper, J. – Poddubnyy, D.: Axial spondyloarthritis. *Lancet*, 2017, 390, s. 73–84.
- 2 Rudwaleit, M. – van der Heijde, D. – Landewe, R., et al.: The development of assessment of spondyloarthritis international society classification criteria for axial spondyloarthritis (part II): validation and final selection. *Ann Rheum Dis*, 2009, 68, s. 777–783.
- 3 Sieper, J. – van der Heide, D. – Dougados, M.: Efficacy and safety of adalimumab in patients with non-radiographic axial spondyloarthritis results of a randomised, placebo controlled trial (ABILITY-1). *Ann Rheum Dis*, 2013, 72, s. 815–822.
- 4 Braun, J. – Baraliakos, X. – Deodhar, A., et al.: Secukinumab shows sustained efficacy and low structural progression in AS: 4 year results from the MEASURE I study. *Rheumatology*, 2019, 58, s. 859–868.
- 5 van der Heijde, D. – Cheng-Chung Wei, J. – Dougados, M., et al.: Ixekizumab, an interleukin-17A antagonist in the treatment of ankylosing spondylitis or radiographic axial spondyloarthritis in patients previously untreated with biological disease-modifying anti-rheumatic drugs (COAST-V): 16 week results of a phase 3 randomised, double-blind, active-controlled and placebo-controlled trial. *Lancet*, 2018, 392, s. 2441–2451.
- 6 van der Heijde, D. – Song, I.-H. – Pangan, A. L., et al.: Efficacy and safety of upadacitinib in patients with active ankylosing spondylitis (SELECT AXIS 1): a multicentre, randomised, double-blind, placebo-controlled, phase 2/3 trial. *Lancet*, 2019, 394, s. 2108–2117.
- 7 Watad, A. – Bridgewood, C. – Russel, T., et al.: The early phases of ankylosing spondylitis emerging insights from clinical and basic science. *Front Immunol*, 2018, 9, s. 2668.
- 8 Hammitsch, A. – Lorenz, G. – Moog, P.: Impact of Janus Kinase inhibition on treatment of axial spondyloarthritis. *Front Immunol*, 2020, <https://doi.org/10.3389/fimmu.2020.591176>.
- 9 Fleischmann, R. – Mysler, E. – Hall, S.: Efficacy and safety of tofacitinib monotherapy, tofacitinib with methotrexate and adalimumab with methotrexate in patients with RA (Study ORAL/Strategy). *Lancet*, 2017, 390, s. 457–468.
- 10 Genovese, M. C. – Kremer, J. – Zamani, O.: Baricitinib in patients with refractory rheumatoid arthritis. *N Engl J Med*, 2016, 374, s. 1243–1252.
- 11 Burmester, G. – Kremer, J. M. – van der Bosch, F., et al.: Safety and efficacy of upadacitinib in patients with rheumatoid arthritis and inadequate response to conventional csDMARD/SELECT Next: a randomised, double blind, placebo controlled phase 3 trial. *Lancet*, 2018, 391, s. 2503–2512.
- 12 Genovese, M. – Westhovens, R. – Meuleeners, L., et al.: Effect of filgotinib, a selective JAK 1 inhibitor, with and without MTX in patients with RA. *Arthritis Res Ther*, 2018, 20, s. 57.
- 13 Fleischmann, R. – Pangan, A. L. – Song, I.-H., et al.: Upadacitinib versus placebo or adalimumab in patients with rheumatoid arthritis and an inadequate response to methotrexate: results of a phase III, double-blind, randomized controlled trial. *Arthritis Rheumatol*, 2019, 71, s. 1788–1800.
- 14 van der Heijde, D. – Deodhar, A. – Wei, J. C., et al.: Tofacitinib in patients with ankylosing spondylitis a phase II, 16 week randomised, placebo controlled study. *Ann Rheum Dis*, 2017, 76, s. 1340–1347.
- 15 van der Heijde, D. – Baraliakos, X. – Gensler, L., et al.: Efficacy and safety of filgotinib, a selective Janus kinase 1 inhibitor in patients with active ankylosing spondylitis (TORTUGA) results from a randomised, placebo controlled, phase 2 trial. *Lancet*, 2018, 392, s. 2378–2387.
- 16 Cohen, S. B. – Tanaka, Y. – Mariette, X., et al.: Long-term safety of tofacitinib for the treatment of rheumatoid arthritis up to 8.5 years: integrated safety analysis of the data from global clinical trials. *Ann Rheum Dis*, 2017, 76, s. 1253–1262.
- 17 Various European Medicines Agency, emea-europa.eu (2020). Dosupné z: <https://www.ema.europa.eu/en>.
- 18 Vallejo-Yague, E. – Weiler, S. – Burden, A. M.: OP0237: Tromboembolic safety profile of tofacitinib and baricitinib: an analysis of WHO Vigibase. *Ann Rheum Dis*, 2020, 79, suppl. 1, s. 150.
- 19 Mease, P. – Charles-Shoeman, Ch. – Cohen, S., et al.: Incidence of venous and arterial thromboembolic events reported in the tofacitinib rheumatoid arthritis, psoriasis and psoriatic arthritis development programmes and from real-world data. *Ann Rheum Dis*, 2020, 79, s. 1400–1413.

# Obtížně léčitelná revmatoidní artritida – stanovisko EULAR

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- 1 Šenolt, L.: Revmatoidní artritida. *Vnitř Lek*, 2018, 64, s. 98–106.
- 2 Smolen, J. S. – Breedveld, F. C. – Burmester, G. R., et al.: Treating rheumatoid arthritis to target: 2014 update of the recommendations of an international task force. *Ann Rheum Dis*, 2016, 75, s. 3–15.
- 3 Aletaha, D. – Neogi, T. – Silman, A. J., et al.: 2010 rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Ann Rheum Dis*, 2010, 69, s. 1580–1588.
- 4 Šenolt, L.: Emerging therapies in rheumatoid arthritis: focus on monoclonal antibodies. *F1000 Res*, 2019, 8, F1000 Faculty Rev, 1549.
- 5 Smolen, J. S. – Landewé, R. B. M. – Bijlsma, J. W. J., et al.: EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*, 2020, 79, s. 685–699.
- 6 Fraenkel, L. – Bathon, J. M. – England, B. R., et al.: American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*, 2021, 73, s. 1108–1123.
- 7 Šenolt, L. – Mann, H. – Závada, J. – Pavelka, K. – Vencovský, J.: Doporučení České revmatologické společnosti pro farmakoterapii revmatoidní artridy 2017. *Česká revmatologie*, 2017, 25, s. 8–16, 18–24.
- 8 de Hair, M. J. H. – Jacobs, J. W. G. – Schoneveld, J. L. M., et al.: Difficult-to-treat rheumatoid arthritis: an area of unmet clinical need. *Rheumatology*, 2018, 57, s. 1135–1144.
- 9 Lewis, M. J. – Barnes, M. R. – Blighe, K., et al.: Molecular portraits of early rheumatoid arthritis identify clinical and treatment response phenotypes. *Cell Rep*, 2019, 28, s. 2455–2470.
- 10 Lliso-Ribera, G. – Humby, F. – Lewis, M., et al.: Synovial tissue signatures enhance clinical classification and prognostic/treatment response algorithms in early inflammatory arthritis and predict requirement for subsequent biological therapy: results from the pathology of early arthritis cohort (PEAC). *Ann Rheum Dis*, 2019, 78, s. 1642–1652.
- 11 Nerviani, A. – Di Cicco, M. – Mahto, A., et al.: A Pauci-immune synovial phenotype predicts inadequate response to TNFα-blockade in rheumatoid arthritis patients. *Front Immunol*, 2020, 11, s. 845.
- 12 Petrovká, N. – Pražlerová, K. – Vencovský, J. – Šenolt, L. – Filková, M.: The preclinical phase of rheumatoid arthritis: From risk factors to prevention of arthritis. *Autoimmun Rev*, 2021, 20, s. 102797.
- 13 Guo, S. – Xu, L. – Chang, C., et al.: Epigenetic regulation mediated by methylation in the pathogenesis and precision medicine of rheumatoid arthritis. *Front Genet*, 2020, 11, s. 811.
- 14 Sparks, J. A. – Costenbader, K. H.: Genetics, environment, and gene-environment interactions in the development of systemic rheumatic diseases. *Rheum Dis Clin North Am*, 2014, 40, s. 637–657.
- 15 Vittecoq, O. – Richard, L. – Banse, C., et al.: The impact of smoking on rheumatoid arthritis outcomes. *Joint Bone Spine*, 2018, 85, s. 135–138.
- 16 Schaeverbeke, T. – Truchetet, M. E. – Kostine, M., et al.: Immunogenicity of biologic agents in rheumatoid arthritis patients: lessons for clinical practice. *Rheumatology*, 2016, 55, s. 210–220.
- 17 Sakai, R. – Tanaka, M. – Nanki, T., et al.: REAL Study Group: Drug retention rates and relevant risk factors for drug discontinuation due to adverse events in rheumatoid arthritis patients receiving anticytokine therapy with different target molecules. *Ann Rheum Dis*, 2012, 71, s. 1820–1826.
- 18 Hope, H. F. – Hyrich, K. L. – Anderson, J., et al.: RAMS co-investigators: The predictors of and reasons for non-adherence in an observational cohort of patients with rheumatoid arthritis commencing methotrexate. *Rheumatology*, 2020, 59, s. 213–223.
- 19 Poudel, D. – George, M. D. – Baker, J. F.: The impact of obesity on disease activity and treatment response in rheumatoid arthritis. *Curr Rheumatol Rep*, 2020, 22, s. 56.
- 20 Liu, Y. – Hazlewood, G. S. – Kaplan, G. G., et al.: Impact of obesity on remission and disease activity in rheumatoid arthritis: a systematic review and meta-analysis. *Arthritis Care Res*, 2017, 69, s. 157–165.
- 21 Roodenrijns, N. M. T. – de Hair, M. J. H. – van der Goes, M. C., et al.: Whole EULAR Task Force on development of EULAR recommendations for the comprehensive management of difficult-to-treat rheumatoid arthritis. Characteristics of difficult-to-treat rheumatoid arthritis: results of an international survey. *Ann Rheum Dis*, 2018, 77, s. 1705–1709.
- 22 Nagy, G. – Roodenrijns, N. M. T. – Welsing, P. M., et al.: EULAR definition of difficult-to-treat rheumatoid arthritis. *Ann Rheum Dis*, 2021, 80, s. 31–35.
- 23 Buch, M. H. – Eyre, S. – McGonagle, D.: Persistent inflammatory and non-inflammatory mechanisms in refractory rheumatoid arthritis. *Nat Rev Rheumatol*, 2021, 17, s. 17–33.
- 24 Smolen, J. S. – van der Heijde, D. – Machold, K. P., et al.: Proposal for a new nomenclature of disease-modifying antirheumatic drugs. *Ann Rheum Dis*, 2014, 73, s. 3–5.

# Terapie revmatoidní artridy etanerceptem je účinnější u pacientů se střední než vysokou aktivitou nemoci

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- 1 Maini, R. – St Clair, E. W. – Breedveld, F., et al.: Infliximab (chimeric anti-tumour necrosis factor alpha monoclonal antibody) versus placebo in rheumatoid arthritis patients receiving concomitant methotrexate: a randomised phase III trial. ATTRACT Study Group. *Lancet*, 1999, 354, s. 1932–1939.
- 2 Tanaka, Y.: The JAK inhibitors: do they bring a paradigm shift for the management of rheumatic diseases? *Rheumatology*, 2019, 58, suppl. 1, s. i1–i3.
- 3 Smolen, J. – Landewé, R. – Bijlsma, J., et al.: EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*, 2020, 79, s. 685–699.
- 4 Šenolt, L. – Mann, H. – Závada, J. – Pavelka, K. – Vencovský, J.: Doporučení České revmatologické společnosti pro farmakoterapii revmatoidní artridy 2017. *Česká revmatologie*, 2017, 25, s. 8–24.
- 5 Smolen, J. – Aletaha, D. – Bijlsma, J. W. Q., et al.: Treating rheumatoid arthritis to target. Recommendations of an international task force. *Ann Rheum Dis*, 2010, 69, s. 631–637.
- 6 Emery, P. – Breedveld, F. C. – Hall, S., et al.: Comparison of methotrexate monotherapy with a combination of methotrexate and etanercept in active, early, moderate to severe rheumatoid arthritis (COMET): a randomised, double-blind, parallel treatment trial. *Lancet*, 2008, 372, s. 375–382.
- 7 Linde, L. – Sorensen, J. – Ostergaard, M., et al.: Does clinical remission lead to normalization of EQ-5D in patients with rheumatoid arthritis and is selection of remission criteria important. *J Rheumatol*, 2010, 37, s. 2, doi10.3899/jrheum.090898.
- 8 Katchamart, W. – Johnson, S., et al.: Predictors for remission in RA patients: A systematic review. *Arthritis Care Research*, 2010, 62, s. 1128–1143.
- 9 Kavanaugh, A. – Keystone, E. – Greenberg, J. D., et al.: Benefit of biologics initiation in moderate versus severe RA. Evidence from United States registry. *Rheumatology*, 2017, 56, s. 1095–1101.

- 10 Keystone, E. – Freundlich, B. – Schiff, M., et al.: Patients with moderate rheumatoid arthritis (RA) achieve better disease activity states with etanercept treatment than patients with severe RA. *J Rheumatol*, 2009, 36, s. 522–531.
- 11 Pavelka, K. – Nekvindová, L.: Dosažení cíle léčby revmatoidní artritidy je častější u pacientů se střední aktivitou než s vysokou aktivitou nemoci v reálné klinické praxi národního registru biologické léčby ATTRA. *Česká revmatologie*, 2021, přijato k publikaci.

## Současné postavení biosimilárních léků v terapii revmatických chorob

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- 1 Doan, Q. V. – Chiou, C. F. – Dubois, R. W.: Review of eight pharmacoeconomic studies of the value of biologic DMARDs (adalimumab, etanercept, and infliximab) in the management of rheumatoid arthritis. *J Manag Care Pharm*, 2006, 12, s. 555–569.
- 2 Tanaka, E. – Inoue, E. – Yamaguchi, R., et al.: Pharmacoeconomic analysis of biological disease-modifying antirheumatic drugs in patients with rheumatoid arthritis based on real-world data from the IORRA observational cohort study in Japan. *Mod Rheumatol*, 2017, 27, s. 227–236.
- 3 Smolen, J. S. – Goncalves, J. – Quinn, M., et al.: Era of biosimilars in rheumatology: reshaping the healthcare environment. *RMD Open*, 2019, 5, s. e000900.
- 4 Smolen, J. S. – Landewé, R. B. M. – Bijlsma, J. W. J., et al.: EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*, 2020, 79, s. 685–699.
- 5 European Medicines Agency. Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues. Dostupné z: [https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-similar-biological-medicinal-products-containing-biotechnology-derived-proteins-active\\_en2.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-similar-biological-medicinal-products-containing-biotechnology-derived-proteins-active_en2.pdf), vyhledáno 11. 8. 2021.
- 6 US Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). Scientific considerations in demonstrating biosimilarity to a reference product: guidance for industry. Dostupné z: <https://www.fda.gov/media/82647/download>, vyhledáno 11. 8. 2021.
- 7 Tesser, J. – Furst, D. – Jacobs, I.: Biosimilars and the extrapolation of indications for inflammatory conditions. *Biologics*, 2017, 11, s. 5–11.
- 8 Zhao, S. – Chadwick, L. – Myuler, E., et al.: Review of biosimilar trials and data on adalimumab in rheumatoid arthritis. *Curr Rheumatol Rep*, 2018, 20, s. 57.
- 9 Kay, J. – Schoels, M. M. – Dörner, T., et al.: Task Force on the Use of Biosimilars to Treat Rheumatological Diseases. Consensus-based recommendations for the use of biosimilars to treat rheumatological diseases. *Ann Rheum Dis*, 2018, 77, s. 165–174.
- 10 Weinblatt, M. E. – Baranauskaitė, A. – Dokoupilova, E., et al.: Switching from reference adalimumab SB5 (adalimumab biosimilar) in patients with rheumatoid arthritis: fifty-two-week phase III randomized study results. *Arthritis Rheumatol*, 2018, 70, s. 832–840.
- 11 Willard, P. – Jeka, S. – Dokoupilova, E., et al.: Switching to biosimilar SDZ-ADL in patients with moderate-to-severe active rheumatoid arthritis: 48-week efficacy, safety and immunogenicity results from the phase III, randomized, double-blind ADMYRA study. *Bio Drugs*, 2020, 34, s. 809–823.
- 12 Jørgensen, K. K. – Olsen, I. C. – Goll, G. L., et al.: NOR-SWITCH Study Group: Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial. *Lancet*, 2017, 389, s. 2304–2316.
- 13 Goll, G. L. – Jørgensen, K. K. – Sexton, J., et al.: Long-term efficacy and safety of biosimilar infliximab (CT-P13) after switching from originator infliximab: open-label extension of the NOR-SWITCH trial. *J Intern Med*, 2019, 285, s. 653–669.
- 14 Griffiths, C. E. M. – Thaçi, D. – Gerdes, S., et al.: The EGALITY study: a confirmatory, randomized, double-blind study comparing the efficacy, safety and immunogenicity of GP2015, a proposed etanercept biosimilar, vs. the originator product in patients with moderate-to-severe chronic plaque-type psoriasis. *Br J Dermatol*, 2017, 176, s. 928–938.
- 15 Gerdes, S. – Thaçi, D. – Griffiths, C. E. M., et al.: Multiple switches between GP2015, an etanercept biosimilar, with originator product do not impact efficacy, safety and immunogenicity in patients with chronic plaque-type psoriasis: 30-week results from the phase 3, confirmatory EGALITY study. *J Eur Acad Dermatol Venereol*, 2018, 32, s. 420–427.
- 16 Dostupné z: <https://www.fda.gov/drugs/biosimilars/prescribing-biologics-and-interchangeable-products>, vyhledáno 11. 8. 2021.
- 17 Dostupné z: [https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals\\_cs.pdf](https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_cs.pdf), vyhledáno 11. 8. 2021.
- 18 Pharmacompass. Top drugs by sales in 2017: who sold the blockbuster drugs? 29 March 2018. Dostupné z: <https://www.pharmacompass.com/radio-compass-blog/top-drugs-by-sales-in-2017-who-sold-the-blockbuster-drugs>, vyhledáno 11. 8. 2021.
- 19 Quintiles, I. M. S.: The impact of biosimilar competition in Europe. Dostupné z: [https://ec.europa.eu/growth/content/impactbiosimilar-competition-price-volume-and-market-share-update-2017-0\\_en](https://ec.europa.eu/growth/content/impactbiosimilar-competition-price-volume-and-market-share-update-2017-0_en), vyhledáno 11. 8. 2021.
- 20 Troein, P. – Newton, M. – Scott, K.: Impact of biosimilars competition in Europe. IQVIA December 2020 White paper. Dostupné z: [https://ec.europa.eu/health/sites/default/files/human-use/docs/biosimilar-competition\\_en.pdf](https://ec.europa.eu/health/sites/default/files/human-use/docs/biosimilar-competition_en.pdf), vyhledáno 11. 8. 2021.
- 21 Planès, S. – Villier, C. – Mallaret, M.: The nocebo effect of drugs. *Pharmacol Res Perspect*, 2016, 4, s. e00208.
- 22 Palermo, S. – Benedetti, F. – Costa, T., et al.: Pain anticipation: an activation likelihood estimation meta-analysis of brain imaging studies. *Hum Brain Mapp*, 2015, 36, s. 1648–1661.
- 23 Carillo, E. – Benedetti, F.: Different contexts, different pains, different experiences. *Neuroscience*, 2016, 338, s. 19–26.
- 24 Tweehuysen, L. – van den Bemt, B. J. F. – van Ingen, I. L., et al.: Subjective complaints as the main reason for biosimilar discontinuation after open-label transition from reference infliximab to biosimilar infliximab. *Arthritis Rheumatol*, 2018, 70, s. 60–68.
- 25 Tweehuysen, L. – Huiskes, V. J. B. – van den Bemt, B. J. F., et al.: Higher acceptance and persistence rates after biosimilar transitioning in patients with a rheumatic disease after employing an enhanced communication strategy. *Ann Rheum Dis*, 2017, 76, s. 557.

## Terapie velmi časné revmatoidní artritidy s přítomností rizikových faktorů špatného vývoje s možností uplatnění certolizumab pegolu

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- 1 Smolen, J. S. – Aletaha, D. – McInnes, I. B.: Rheumatoid arthritis. *Lancet*, 2016, 388, s. 2023–2038.
- 2 Nam, J. L. – Ramiro, S. – Gaujoux-Viala, C., et al.: Efficacy of biological disease-modifying antirheumatic drugs: a systematic literature review informing the 2013 update of the EULAR recommendations for the management of rheumatoid arthritis. *Ann Rheum Dis*, 2014, 73, s. 516–528.
- 3 Smolen, J. S. – Landewé, R. B. M. – Bijlsma, J. W., et al.: EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*, 2020, 79, s. 685–699.
- 4 Smolen, J. S. – Landewé, R. – Bijlsma, J. W., et al.: EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis*, 2017, 76, s. 960–977.
- 5 Nam, J. L. – Villeneuve, E. – Hensor, E. M. A., et al.: Remission induction comparing infliximab and high-dose intravenous steroid, followed by treat-to-target: a double-blind, randomised, controlled trial in new-onset, treatment-naïve, rheumatoid arthritis (the IDEA study). *Ann Rheum Dis*, 2014, 73, s. 75–85.
- 6 Burmester, G. R. – Rigby, W. F. – van Vollenhoven, R. F., et al.: Tocilizumab in early progressive rheumatoid arthritis: FUNCTION, a randomised controlled trial. *Ann Rheum Dis*, 2016, 75, s. 1081–1091.
- 7 Emery, P. – Bingham, C. O. – Burmester, G. R., et al.: Certolizumab pegol in combination with dose-optimised methotrexate in DMARD-naïve patients with early, active rheumatoid arthritis with poor prognostic factors: 1-year results from C-EARLY, a randomised, double-blind, placebo-controlled phase III study. *Ann Rheum Dis*, 2017, 76, s. 96–104.
- 8 Atsumi, T. – Yamamoto, K. – Takeuchi, T., et al.: The first double-blind, randomised, parallel-group certolizumab pegol study in methotrexate-naïve early rheumatoid arthritis patients with poor prognostic factors, C-OPERA, shows inhibition for radiographic progression. *Ann Rheum Dis*, 2016, 75, s. 75–83.
- 9 Tahakashi, C. – Kaneko, Y. – Okano, H.: Methotrexate polyglutamates in erythrocytes correlates with clinical response in Japanese patients with rheumatoid arthritis. *Ann Rheum Dis*, 2014, 73, suppl. 2, s. 213–219.
- 10 Bejarano, V. – Conaghan, P. G. – Quinn, M., et al.: Benefits 8 years after a remission induction regime with an infliximab and methotrexate combination in early rheumatoid arthritis. *Rheumatology*, 2010, 49, s. 1971–1974.
- 11 Bijlsma, J. W. – Welsing, P. M. J. – Woodworth, T. G., et al.: Early rheumatoid arthritis treated with tocilizumab, MTX, or their combination (U-Act-Early): a multicentre, randomised, double blind, double-dummy, strategy trial. *Lancet*, 2016, 388, s. 343–355.
- 12 Fleischmann, R. – Takeuchi, T. – Schlichting, G., et al.: Baricitinib, methotrexate or baricitinib plus methotrexate in patients with early RA who have received limited or no treatment with disease-modifying antirheumatic drugs (DMARD) phase 3 trial results (abstract). *Arthritis Rheum*, 2015, 67, suppl. 10.
- 13 van Vollenhoven, R. – Takeuchi, T. – Pangan, A. L., et al.: Efficacy and safety of upadacitinib monotherapy in methotrexate-naïve patients with moderately-to-severely active rheumatoid arthritis (SELECT-EARLY): a multicenter, multi-country, randomized, double-blind, active comparator-controlled trial. *Arthritis Rheumatol*, 2020, 72, s. 1607–1620.
- 14 Smolen, J. S. – Emery, P. – Fleischmann, R., et al.: Adjustment of therapy in rheumatoid arthritis on the basis of achievement of stable low disease activity with adalimumab plus MTX or MTX alone: the randomised controlled OPTIMA trial. *Lancet*, 2014, 383, s. 321–332.
- 15 Atsumi, T. – Tanaka, Y. – Yamamoto, K., et al.: Clinical benefit of 1-year certolizumab pegol (CZP) add-on therapy to methotrexate treatment in patients with early rheumatoid arthritis was observed following CZP discontinuation: 2-year results of the C-OPERA study, a phase III randomised trial. *Ann Rheum Dis*, 2017, 76, s. 1348–1356.
- 16 Quinn, M. A. – Gonaghan, P. G. – O'Connor, P. J., et al.: Very early treatment with infliximab in addition to methotrexate in early, poor-prognosis rheumatoid arthritis reduces magnetic resonance imaging evidence of synovitis and damage, with sustained benefit after infliximab withdrawal: results from a twelve-month randomized, double-blind, placebo-controlled trial. *Arthritis Rheum*, 2005, 52, s. 27–35.
- 17 Breedveld, F. C. – Weisman, M. H. – Kavanaugh, A. F., et al.: The PREMIER study: A multicenter, randomized, double-blind clinical trial of combination therapy with adalimumab plus methotrexate versus methotrexate alone or adalimumab alone in patients with early, aggressive rheumatoid arthritis who had not had previous methotrexate treatment. *Arthritis Rheum*, 2006, 54, s. 26–37.
- 18 Emery, P. – Breedveld, F. C. – Hall, S., et al.: Comparison of methotrexate monotherapy with a combination of methotrexate and etanercept in active, early, moderate to severe rheumatoid arthritis (COMET): a randomised, double-blind, parallel treatment trial. *Lancet*, 2008, 372, s. 375–382.
- 19 Emery, P. – Fleischmann, R. – van der Heijde, D., et al.: The effects of golimumab on radiographic progression in rheumatoid arthritis: results of randomized controlled studies of golimumab before methotrexate therapy and golimumab after methotrexate therapy. *Arthritis Rheum*, 2011, 63, s. 1200–1210.
- 20 Emery, P. – Bingham, C. O. – Burmester, G. R., et al.: Certolizumab pegol in combination with dose-optimised methotrexate in DMARD-naïve patients with early, active rheumatoid arthritis with poor prognostic factors: 1-year results from C-EARLY, a randomised, double-blind, placebo-controlled phase III study. *Ann Rheum Dis*, 2017, 76, s. 96–104.
- 21 Espinoza, F. – Fabre, S. – Pers, Y. M.: Remission-induction therapies for early rheumatoid arthritis: evidence to date and clinical implications. *Ther Adv Musculoskeletal Dis*, 2016, 8, s. 107–118.
- 22 Van Nies J. A. B. – Tsionaka, R. – Gaujoux-Viala, C., et al.: Evaluating relationships between symptom duration and persistence of rheumatoid arthritis: does a window of opportunity exist? Results on the Leiden early arthritis clinic and ESPoir cohorts. *Ann Rheum Dis*, 2015, 74, s. 806–812.

# Bezpečnost a účinnost sarilumabu v přímém srovnání s tocilizumabem v léčbě revmatoidní artridy – Shrnutí výsledků studie ASCERTAIN a její dlouhodobé extenze v rámci studie EXTEND

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- 1 Emery, P. – Rondon, J. – Parrino, J., et al.: Safety and tolerability of subcutaneous sarilumab and intravenous tocilizumab in patients with rheumatoid arthritis. *Rheumatology*, 2019, 58, s. 849–858.
- 2 Emery, P. – van Hoogstraten, H. – Thangavelu, K., et al.: Subcutaneous sarilumab in patients with rheumatoid arthritis who previously received subcutaneous sarilumab or intravenous tocilizumab: an open-label extension of a randomized clinical trial. *ACR Open Rheumatol*, 2020, 2, s. 672–680.

# Bezpečnost tofacitinibu v běžné klinické praxi u nemocných s revmatoidní artridou

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- 1 Vashishth, P. – Sayles, H. – Cannella, A. C., et al.: Generalizability of patients with rheumatoid arthritis in biologic agent clinical trials. *Arthritis Care Res*, 2016, 68, s. 1478–1488.
- 2 Álvaro-Gracia, J. M. – García-Llorente, J. F. – Valderrama, M., et al.: Update on the safety profile of tofacitinib in rheumatoid arthritis from clinical trials to real-world studies: a narrative review. *Rheumatol Ther*, 2021, 8, s. 17–40.
- 3 Charles-Schoeman, C. – DeMasi, R. – Valdez, H., et al.: Risk factors for major adverse cardiovascular events in phase III and long-term extension studies of tofacitinib in patients with rheumatoid arthritis. *Arthritis Rheumatol*, 2019, 71, s. 1450–1459.
- 4 McInnes, I. B. – Kim, H. Y. – Lee, S. H., et al.: Open-label tofacitinib and double-blind atorvastatin in rheumatoid arthritis patients: a randomised study. *Ann Rheum Dis*, 2014, 73, s. 124–131.
- 5 Xie, W. – Huang, Y. – Xiao, S., et al.: Impact of Janus kinase inhibitors on risk of cardiovascular events in patients with rheumatoid arthritis: systematic review and meta-analysis of randomised controlled trials. *Ann Rheum Dis*, 2019, 78, s. 1048–1054.
- 6 Cohen, S. – Curtis, J. R. – DeMasi, R., et al.: World wide, 3-year, post-marketing surveillance experience with tofacitinib in rheumatoid arthritis. *Rheumatol Ther*, 2018, 5, s. 283–291.
- 7 Kremer, J. – Bingham, C. – Cappelli, L., et al.: Post-approval comparative safety study of tofacitinib and biologic DMARDs: five-year results from a US-based rheumatoid arthritis registry. *Ann Rheum Dis*, 2019, 78, s. 82–83.
- 8 Wollenhaupt, J. – Lee, E. B. – Curtis, J. R., et al.: Safety and efficacy of tofacitinib for up to 9.5 years in the treatment of rheumatoid arthritis: final results of a global, open-label, long-term extension study. *Arthritis Res Ther*, 2019, 21, s. 89.
- 9 Mease, P. – Charles-Schoeman, C. – Cohen, S., et al.: Incidence of venous and arterial thromboembolic events reported in the tofacitinib rheumatoid arthritis, psoriasis and psoriatic arthritis development programmes and from real-world data. *Ann Rheum Dis*, 2020, 79, s. 1400–1413.
- 10 Sivaraman, P. – Cohen, S. B.: Malignancy and Janus kinase inhibition. *Rheum Dis Clin North Am*, 2017, 43, s. 79–93.
- 11 Winthrop, K. L. – Curtis, J. R. – Lindsey, S., et al.: Herpes zoster and tofacitinib: clinical outcomes and the risk of concomitant therapy. *Arthritis Rheumatol*, 2017, 69, s. 1960–1968.
- 12 Curtis, J. R. – Xie, F. – Yang, S., et al.: Risk for herpes zoster in tofacitinib-treated rheumatoid arthritis patients with and without concomitant methotrexate and glucocorticoids. *Arthritis Care Res*, 2019, 71, s. 1249–1254.

# Hluboká žilní trombóza a plicní embolie u nemocných se zánětlivými revmatickými onemocněními

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- 1 Beckman, M. G. – Hooper, W. C. – Critchley, S. E., et al.: Venous thromboembolism: a public health concern. *Am J Prev Med*, 2010, 38, s. 495–501.
- 2 Blann, A. D. – Lip, G. Y.: Virchow's triad revisited: the importance of soluble coagulation factors, the endothelium, and platelets. *Thromb Res*, 2001, 101, s. 321–327.
- 3 Hirmerová, J.: Trombofilní stav – testovat či netestovat? *Interni Med*, 2019, 21, s. 187–191.
- 4 Esmon, C. T.: The interactions between inflammation and coagulation. *Br J Haematol*, 2005, 131, s. 417–430.
- 5 Silvestri, E. – Scalera, A. – Emmi, G., et al.: Thrombosis in autoimmune diseases: a role for immunosuppressive treatments? *Semin Thromb Hemost*, 2016, 42, s. 650–661.
- 6 Andreoli, L. – Bertsias, G. K. – Agmon-Levin, N., et al.: EULAR recommendations for women's health and the management of family planning, assisted reproduction, pregnancy and menopause in patients with systemic lupus erythematosus and/or antiphospholipid syndrome. *Ann Rheum Dis*, 2017, 76, s. 476–485.
- 7 Levi, M. – van der Poll, T.: Inflammation and coagulation. *Crit Care Med*, 2010, 38, suppl. 2, s. S26–S34.
- 8 Green, D.: Coagulation cascade. *Hemodial Int*, 2006, suppl. 2, s. S2–S4.
- 9 Periyah, M. H. – Halim, A. S. – Mat Saad, A. Z.: Mechanism action of platelets and crucial blood coagulation pathways in hemostasis. *Int J Hematol Oncol Stem Cell Res*, 2017, 11, s. 319–327.
- 10 Zelová, H. – Hošek, J.: TNF- $\alpha$  signalling and inflammation: interactions between old acquaintances. *Inflamm Res*, 2013, 62, s. 641–651.
- 11 Lentz, S. R. – Tsiang, M. – Sadler, J. E.: Regulation of thrombo-modulin by tumor necrosis factor-alpha: comparison of transcriptional and posttranscriptional mechanisms. *Blood*, 1991, 77, s. 542–550.
- 12 Archipoff, G. – Beretz, A. – Freyssinet, J. M., et al.: Heterogeneous regulation of constitutive thrombomodulin or inducible tissue-factor activities on the surface of human saphenous vein endothelial cells in culture following stimulation by interleukin-1, tumour necrosis factor, thrombin or phorbol ester. *Biochem J*, 1991, 273, part 3, s. 679–684.
- 13 Nawroth, P. P. – Handley, D. A. – Esmon, C. T., et al.: Interleukin 1 induces endothelial cell procoagulant while suppressing cell-surface anticoagulant activity. *Proc Natl Acad Sci U S A*, 1986, 83, s. 3460–3464.
- 14 Rijken, D. C. – Lijnen, H. R.: New insights into the molecular mechanisms of the fibrinolytic system. *J Thromb Haemost*, 2009, 7, s. 4–13.
- 15 Arıbasılı, M. – İnanc, N. – Baykan, O. A., et al.: The effects of TNF alpha inhibition on plasma fibrinolytic balance in patients with chronic inflammatory rheumatic disorders. *Clin Exp Rheumatol*, 2006, 24, s. 580–583.
- 16 Denny, M. F. – Yalavarthi, S. – Zhao, W., et al.: A distinct subset of proinflammatory neutrophils isolated from patients with systemic lupus erythematosus induces vascular damage and synthesizes type I IFNs. *J Immunol*, 2010, 184, s. 3284–3297.
- 17 Fuchs, T. A. – Abed, U. – Goosmann, C., et al.: Novel cell death program leads to neutrophil extracellular traps. *J Cell Biol*, 2007, 176, s. 231–241.
- 18 Molander, V. – Bower, H. – Frisell, T., et al.: Risk of venous thromboembolism in rheumatoid arthritis, and its association with disease activity: a nationwide cohort study from Sweden. *Ann Rheum Dis*, 2021, 80, s. 169–175.
- 19 Fujieda, Y. – Amengual, O.: New insights into the pathogenic mechanisms and treatment of arterial thrombosis in antiphospholipid syndrome. *Eur J Rheumatol*, 2020, 8, s. 93–99.
- 20 Kazzaz, N. M. – McCune, W. J. – Knight, J. S.: Treatment of catastrophic antiphospholipid syndrome. *Curr Opin Rheumatol*, 2016, 28, s. 218–227.
- 21 Pignatelli, P. – Ettorre, E. – Menichelli, D., et al.: Seronegative antiphospholipid syndrome: refining the value of "non-criteria" antibodies for diagnosis and clinical management. *Haematologica*, 2020, 105, s. 562–572.
- 22 Rodziewicz, M. – D'Cruz, D. P.: An update on the management of antiphospholipid syndrome. *Ther Adv Musculoskeletal Dis*, 2020, 12, 1759720X20910855.
- 23 Vardanyan, S. – Ginosyan, K. – Vardanyan, V., et al.: SAT0194 lack of efficacy of rivaroxaban in the Treatment of antiphospholipid syndrome and clinical significance of antiphospholipid antibodies. *Ann Rheum Dis*, 2020, 79, s. 1039, dostupné z: <http://dx.doi.org/10.1136/annrheumdis-2020-3822>, vyhledáno 19. 7. 2021.
- 24 Girolami, A. – Cosi, E. – Tasinato, V., et al.: Drug-induced thrombotic or prothrombotic states: an underestimated clinical problem that involves both legal and illegal compounds. *Clin Appl Thromb Haemost*, 2017, 23, s. 775–785.
- 25 Marwali, M. R. – Mehta, J. L.: COX-2 inhibitors and cardiovascular risk: Inferences based on biology and clinical studies. *Thromb Haemost*, 2006, 96, s. 401–406.
- 26 Krötz, F. – Struthmann, L.: A review on the risk of myocardial infarction associated with the NSAID diclofenac. *Cardiovasc Hematol Disord Drug Targets*, 2010, 10, s. 53–62.
- 27 Papp, J. – Sandor, B. – Vamos, Z., et al.: Antiplatelet effect of acetylsalicylic acid, metamizole and their combination – in vitro and in vivo comparisons. *Clin Hemorheol Microcirc*, 2014, 56, s. 1–12.
- 28 Johannesson, S. A. – Horváth-Puhó, E. – Dekkers, O. M., et al.: Use of glucocorticoids and risk of venous thromboembolism: a nationwide population-based case-control study. *JAMA Intern Med*, 2013, 173, s. 743–752.
- 29 Al Sahaw, S. – Zhang, X. – Zhu, B., et al.: Effect of corticosteroid use by dose on the risk of developing organ damage over time in systemic lupus erythematosus – the Hopkins Lupus Cohort. *Lupus Sci Med*, 2015, 2, s. e000066.
- 30 Kim, S. C. – Solomon, D. H. – Liu, J., et al.: Risk of venous thromboembolism in patients with rheumatoid arthritis: initiating disease-modifying antirheumatic drugs. *Am J Med*, 2015, 128, s. 539.e7–17.
- 31 Mato, A. – Feldman, T. – Zielonka, T., et al.: Rituximab, cyclophosphamide- fractionated, vincristine, doxorubicin and dexamethasone alternating with rituximab, methotrexate and cytarabine overcomes risk features associated with inferior outcomes in treatment of newly diagnosed, high-risk diffuse large B-cell lymphoma. *Leuk Lymphoma*, 2013, 54, s. 2606–2612.
- 32 Belizna, C.: Hydroxychloroquine as an anti-thrombotic in antiphospholipid syndrome. *Autoimmun Rev*, 2015, 14, s. 358–362.
- 33 Petri, M.: Use of hydroxychloroquine to prevent thrombosis in systemic lupus erythematosus and in antiphospholipid antibody positive patients. *Curr Rheumatol Rep*, 2011, 13, s. 77–80.
- 34 Vazquez, S. R. – Rondina, M. T. – Pendleton, R. C.: Azathioprine-induced warfarin resistance. *Ann Pharmacother*, 2008, 42, s. 1118–1123.
- 35 Kim, S. C. – Solomon, D. H. – Liu, J., et al.: Risk of venous thromboembolism in patients with rheumatoid arthritis: initiating disease-modifying antirheumatic drugs. *Am J Med*, 2015, 128, s. 539.e7–17.
- 36 van Vollenhoven, R. F. – Fleischmann, R. M. – Furst, D. E., et al.: Long-term safety of rituximab: final report of the Rheumatoid Arthritis Global Clinical Trial Program over 11 years. *J Rheumatol*, 2015, 42, s. 1761–1766.
- 37 Sarwar, N. – Butterworth, A. S. – Freitag, D. F., et al.: IL6R Genetics

- Consortium Emerging Risk Factors Collaboration. Interleukin-6 receptor pathways in coronary heart disease: a collaborative meta-analysis of 82 studies. *Lancet*, 2012, 379, s. 1205–1213.
- 38 Tracey, D. – Klareskog, L. – Sasso, E. H., et al.: Tumor necrosis factor antagonist mechanisms of action: a comprehensive review. *Pharmacol Ther*, 2008, 117, s. 244–279.
- 39 Nosbaum, A. – Goujon, C. – Fleury, B., et al.: Arterial thrombosis with anti-phospholipid antibodies induced by infliximab. *Eur J Dermatol*, 2007, 17, s. 546–547.
- 40 Virupannavar, S. – Brandau, A. – Guggenheim, C., et al.: Possible association of etanercept, venous thrombosis, and induction of antiphospholipid syndrome. *Case Rep Rheumatol*, 2014, 2014, s. 801072.
- 41 Keystone, E. C. – Genovese, M. C. – Schlichting, D. E., et al.: Safety and efficacy of baricitinib through 128 weeks in an open-label, long-term extension study in patients with rheumatoid arthritis. *J Rheumatol*, 2018, 45, s. 14–21.
- 42 Alicea-Velázquez, N. L. – Boggon, T. J.: The use of structural biology in Janus kinase targeted drug discovery. *Curr Drug Targets*, 2011, 12, s. 546–555.
- 43 Ibrahim, F. – Scott, D. L.: Thromboembolism and Janus kinase inhibitors. *Drug Saf*, 2020, 43, s. 831–833.
- 44 Harzallah, I. – Deblouis, A. – Dréno, B.: Frequency of lupus anticoagulant in COVID-19 patients. *J Thromb Haemost*, 2020, 18, s. 2778.
- 45 Pineton de Chambrun, M. – Frere, C., et al.: High frequency of antiphospholipid antibodies in critically ill COVID-19 patients: a link with hypercoagulability? *J Intern Med*, 2021, 289, s. 422–424.
- 46 Genedbien, Z. – von Frenckell, C. – Ribbens, C., et al.: Systematic analysis of COVID-19 infection and symptoms in a systemic lupus erythematosus population: correlation with disease characteristics, hydroxychloroquine use and immunosuppressive treatments. *Ann Rheum Dis*, 2020, annrheumdis-2020-218244.

## Ixekizumab v léčbě psoriatické artritidy

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- 1 Mease, P. J. – van der Heijde, D. – Ritchlin, C. T., et al.: Ixekizumab, an interleukin-17A specific monoclonal antibody, for the treatment of biologic-naïve patients with active psoriatic arthritis: results from the 24-week randomised, double-blind, placebo-controlled and active (adalimumab)-controlled period of the phase III trial SPIRIT-P1. *Ann Rheum Dis*, 2017, 76, s. 79–87.
- 2 Nash, P. – Kirkham, B. – Okada, M., et al.: Ixekizumab for the treatment of patients with active psoriatic arthritis and an inadequate response to tumour necrosis factor inhibitors: results from the 24-week randomised, double-blind, placebo-controlled period of the SPIRIT-P2 trial. *Lancet*, 2017, 389, s. 2317–2327.
- 3 Mease, P. J. – Smolen, J. S. – Behrens, F., et al.: A head-to-head comparison of the efficacy and safety of ixekizumab and adalimumab in biological-naïve patients with active psoriatic arthritis: 24-week results of a randomised, open-label, blinded-assessor trial. *Ann Rheum Dis*, 2020, 79, s. 123–131.
- 4 Smolen, J. S. – Mease, P. – Tahir, H., et al.: Multicentre, randomised, open-label, parallel-group study evaluating the efficacy and safety of

ixekizumab versus adalimumab in patients with psoriatic arthritis naïve to biological disease-modifying antirheumatic drug: final results by week 52. *Ann Rheum Dis*, 2020, 79, s. 1310–1319.

- 5 Smolen, J. S. – Sebba, A. – Ruderman, E. M., et al.: Efficacy and safety of ixekizumab with or without methotrexate in biologic-naïve patients with psoriatic arthritis: 52-week results from SPIRIT-H2 study. *Rheumatol Ther*, 2020, 7, s. 1021–1035.

## Guselkumab v léčbě psoriatické artritidy

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- 1 Reich, K. – Griffiths, C. E. M. – Gordon, K. B., et al.: Maintenance of clinical response and consistent safety profile with up to 3 years of continuous treatment with guselkumab: Results from the VOYAGE 1 and VOYAGE 2 trials. *Am Acad Dermatol*, 2020, 82, s. 936–945.
- 2 Griffiths, C. E. M. – Papp, K. A. – Song, M., et al.: Continuous treatment with guselkumab maintains clinical responses through 4 years in patients with moderate-to-severe psoriasis: results from VOYAGE 1. *J Dermatol Treat*, 2020, s. 1–9, doi: 10.1080/09546634.2020.1782817.
- 3 Reich, K. – Armstrong, A. W. – Langley, R. G., et al.: Guselkumab versus secukinumab for the treatment of moderate-to-severe psoriasis (ECLIPSE): results from a phase 3, randomised controlled trial. *Lancet*, 2019, 394, s. 831–839.
- 4 Langley, R. G. – Tsai, T. F. – Flavin, S., et al.: Efficacy and safety of guselkumab in patients with psoriasis who have an inadequate response to ustekinumab: results of the randomized, double-blind, phase III NAVIGATE trial. *Br J Dermatol*, 2018, 178, s. 114–123.
- 5 Deodhar, A. – Helliwell, P. S. – Boehncke, W.-H., et al.: Guselkumab in patients with active psoriatic arthritis who were biologic-naïve or had previously received TNF $\alpha$  inhibitor treatment (DISCOVER-1): a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*, 2020, 395, s. 1115–1125.
- 6 Mease, P. J. – Rahman, P. – Gottlieb, A. B., et al.: Guselkumab in biologic-naïve patients with active psoriatic arthritis (DISCOVER-2): a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*, 2020, 395, s. 1126–1136.
- 7 Ritchlin, Ch. T. – Helliwell, P. S. – Boehncke, W.-H., et al.: Guselkumab, an inhibitor of the IL-23p19 subunit, provides sustained improvement in signs and symptoms of active psoriatic arthritis: 1 year results of a phase III randomised study of patients who were biologic-naïve or TNF $\alpha$  inhibitor-experienced. *RMD Open*, 2021, 7, s. e001457.
- 8 McInnes, I. B. – Rahman, P. – Gottlieb, A. B., et al.: Efficacy and safety of guselkumab, an interleukin-23p19-specific monoclonal antibody, through one year in biologic-naïve patients with psoriatic arthritis. *Arthritis Rheumatol*, 2021, 73, s. 604–616.
- 9 Mease, P. J. – Gladman, D. D. – Deodhar, A., et al.: Impact of guselkumab, an interleukin-23 p19 subunit inhibitor, on enthesitis and

dactylitis in patients with moderate to severe psoriatic arthritis: results from a randomised, placebo-controlled, phase II study. *RMD Open*, 2020, 6, s. e001217.

- 10 Mease, P. J. – Helliwell, P. S. – Gladman, D. D., et al.: Efficacy of guselkumab on axial involvement in patients with active psoriatic arthritis and sacroiliitis: a post-hoc analysis of the phase 3 DISCOVER-1 and DISCOVER-2 studies. *Lancet Rheumatol*, 2021, doi: https://doi.org/10.1016/S2665-9913(21)00105-3.
- 11 Rahman, P. – Ritchlin, C. T. – Helliwell, P. S., et al.: Pooled safety results through one year of two phase-3 trials of guselkumab in patients with psoriatic arthritis. *J Rheumatol*, 2021, doi: https://doi.org/10.3899/jrheum.201532.
- 12 Mease, P. J. – McInnes, I. B. – Tam, L.-S., et al.: Comparative effectiveness of guselkumab in psoriatic arthritis: results from systematic literature review and network meta-analysis. *Rheumatology*, 2021, 60, s. 2109–2121.

## Potenciál telemedicíny v revmatologii

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- 1 Patel, S. Y., et al.: Trends in outpatient care delivery and telemedicine during the COVID-19 pandemic in the US. *JAMA Intern Med*, 2021, 181, s. 388–391.
- 2 de Jong, M. J., et al.: Telemedicine for management of inflammatory bowel disease (myIBDcoach): a pragmatic, multicentre, randomised controlled trial. *Lancet*, 2017, 390, s. 959–968.
- 3 Malíčková, K., et al.: Telemedicina a idiopatické střevní záněty – výsledky pilotního projektu IBD asistent. *Gastroent Hepatol*, 2020, 74, s. 18–27.
- 4 Mucha, C., et al.: Doporučené diagnostické a terapeutické postupy pro všeobecné praktické lékaře. *Telemedicina*. Dostupné z: https://www.svl.cz/files/files/Doporucone-postupy/2020/DP-Telemedicina.

pdf, vyhledáno 6. 9. 2021.

5 Committee on Rheumatologic Care: ACR position statement on telemedicine. Dostupné z: https://www.rheumatology.org/Portals/0/Files/Telemedicine-Position-Statement.pdf, vyhledáno 6. 9. 2021.

## Výskyt herpes zoster při biologické a cílené léčbě zánětlivých revmatických onemocnění a možnosti prevence

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- 1 Kim, B. S. – Maverakis, E. – Alexanian, C., et al.: Incidence, clinical features, management, and prevention of herpes zoster in patients receiving antitumor necrosis factor therapy: a clinical review. *J Cutan Med Surg*, 2020, 24, s. 278–284.
- 2 Johnson, R. W. – Alvarez-Pasquin, M. J. – Bijl, M., et al.: Herpes zoster epidemiology, management, and disease and economic burden in Europe: a multidisciplinary perspective. *Ther Adv Vaccines*, 2015, 3, s. 109–120.
- 3 van Assen, S. – Agmon-Levin, N. – Elkayam, O., et al.: EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases. *Ann Rheum Dis*, 2011, 70, s. 414–422.
- 4 Furér, V. – Rondaan, Ch. – Heijstek, M. W., et al.: Incidence and prevalence of vaccine-preventable infections in adult patients with autoimmune inflammatory rheumatic diseases (AIIRD): a systemic literature review informing the 2019 update of the EULAR recommendations for vaccination in adult patients with AIIRD. *RMD Open*, 2019, 5, s. e001041.
- 5 Tanaka, Y. – Atsumi, T. – Amano, K., et al.: Efficacy and safety of baricitinib in Japanese patients with rheumatoid arthritis: Subgroup analyses of four multinational phase 3 randomized trials. *Mod Rheumatol*, 2018, 28, s. 583–591.
- 6 Kawai, K. – Gebremeskel, B. G. – Acosta, C. J.: Systematic review of incidence and complications of herpes zoster: towards a global perspective. *BMJ Open*, 2014, 4, s. e004833.
- 7 Yawn, B. P. – Itzler, R. F. – Wollan, P. C., et al.: Health care utilization and cost burden of herpes zoster in a community population. *Mayo Clin Proc*, 2009, 84, s. 787–794.
- 8 Rondaan, Ch. – Furér, V. – Heijstek, M. W., et al.: Efficacy, immunogenicity and safety of vaccination in adult patients with autoimmune inflammatory rheumatic diseases: a systematic literature review for the 2019 update of EULAR recommendations. *RMD Open*, 2019, 5, s. e001035.
- 9 Furér, V. – Rondaan, Ch. – Heijstek, W. M., et al.: 2019 update of EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases. *Ann Rheum Dis*, 2020, 79, s. 39–52.
- 10 Schneeweiss, S., et al.: Anti-tumor necrosis factor alpha therapy and the risk of serious bacterial infections in elderly patients with rheumatoid arthritis. *Arthritis Rheum*, 2007, 56, s. 1754–1764.
- 11 Ito, M. – Nakano, T. – Kamiya, T., et al.: Effects of tumor necrosis factor alpha on replication of varicella-zoster virus. *Antiviral Res*, 1991, 15, s. 183–192.
- 12 Wang, X. – Zhao, J. – Zhu, S., et al.: Herpes zoster in Crohn's disease during treatment with infliximab. *Eur J Gastroenterol Hepatol*, 2014, 26, s. 237–239.
- 13 Kim, S. Y. – Solomon, H.: Tumor necrosis factor blockade and the risk of viral infection. *Nat Rev Rheumatol*, 2010, 6, s. 165–174.
- 14 Galloway, J. B. – Mercer, L. K. – Moseley, A., et al.: Risk of skin and soft

- tissue infection (including shingles) in patients exposed to anti-tumor necrosis factor therapy: results from British Society for rheumatology biologics register. *Ann Rheum Dis*, 2013, 72, s. 229–234.
- 15 Smitten, A. L. – Choi, H. K. – Hochberg, M. C., et al.: The risk of herpes zoster in patients with rheumatoid arthritis in the United States and the United Kingdom. *Arthritis Rheum*, 2007, 57, s. 1431–1438.
  - 16 Serac, G. – Tubach, F. – Mariette, X., et al.: Risk of herpes zoster in patients receiving anti-TNF-α in the prospective French ratio registry. *J Invest Dermatol*, 2012, 132, s. 726–729.
  - 17 Dworkin, R. – Schmader, K.: The epidemiology and natural history of herpes zoster and postherpetic neuralgia. In: Watson, C. P. N. (ed.): *Herpes zoster and postherpetic neuralgia*. Amsterdam (Nizozemsko, Elsevier, 2001), s. 39–64.
  - 18 McDonald, J. R. – Zeringue, A. L. – Caplan, L., et al.: Herpes zoster risk factors in a national cohort of veterans with rheumatoid arthritis. *Clin Infect Dis*, 2009, 48, s. 1364–1371.
  - 19 Strangfeld, A. – Listing, J. – Rau, R.: Reactivation of herpes virus (HHV-1 and HHV-3) infections is increased in RA patients treated with adalimumab or infliximab. *Ann Rheum Dis*, 2007, 66, s. 118.
  - 20 Strangfeld, A. – Listing, J. – Herzer, P., et al.: Risk of herpes zoster in patients with rheumatoid arthritis treated with anti-TNF-alpha agents. *JAMA*, 2009, 301, s. 737–744.
  - 21 Che, H. – Lukas, C. – Morel, J., et al.: Risk of herpes/herpes zoster during anti-tumor necrosis factor therapy in patients with rheumatoid arthritis. Systematic review and meta-analysis. *Joint Bone Spine*, 2014, 81, s. 215–221.
  - 22 Wendling, D. – Streit, G. – Toussirot, E., et al.: Herpes zoster in patients taking TNFalpha antagonists for chronic inflammatory joint disease. *Joint Bone Spine*, 2008, 75, s. 540–543.
  - 23 Yun, H. – Xie, F. – Delzell, E., et al.: Risks of herpes zoster in patients with rheumatoid arthritis according to biologic disease-modifying therapy. *Arthritis Care Res*, 2015, 67, s. 731–736.
  - 24 Marra, F. – Lo, E. – Kalashnikov, V., et al.: Risk of herpes zoster in individuals on biologics, disease-modifying antirheumatic drugs, and/or corticosteroids for autoimmune diseases: a systematic review and meta-analysis. *Open Forum Infect Dis*, 2016, 3, DOI:10.1093/ofid/ofw250.
  - 25 Adelzadeh, L. – Jourabchi, N. – Wu, J.: The risk of herpes zoster during biological therapy for psoriasis and other inflammatory conditions. *J Eur Acad Dermatol Venereol*, 2014, 28, s. 846–852.
  - 26 Tracey, D. – Klareskog, L. – Sasso, E. H., et al.: Tumor necrosis factor antagonist mechanisms of action: a comprehensive review. *Pharmacol Ther*, 2008, 117, s. 244–279.
  - 27 Furst, D. E. – Schiff, M. H. – Fleischmann, R. M., et al.: Adalimumab, a fully human anti tumor necrosis factor-α monoclonal antibody, and concomitant standard antirheumatic therapy for the treatment of rheumatoid arthritis: results of StAR (safety trial of adalimumab in rheumatoid arthritis). *J Rheumatol*, 2003, 30, s. 2563–2571.
  - 28 Maini, R. N. – Breedveld, F. C. – Kalden, J. R., et al.: Sustained improvement over two years in physical function, structural damage, and signs and symptoms among patients with rheumatoid arthritis treated with infliximab and methotrexate. *Arthritis Rheum*, 2004, 50, s. 1051–1065.
  - 29 Javed, S. – Kamili, Q. U. A. – Mendoza, N., et al.: Possible association of lower rate of postherpetic neuralgia in patients on anti-tumor necrosis factor-α. *J Med Virol*, 2011, 83, s. 2051–2055.
  - 30 Serac, G. – Tubach, F. – Mariette, X., et al.: Risk of herpes zoster in patients receiving anti-TNF-α in the prospective French ratio registry. *J Invest Dermatol*, 2012, 132, s. 726–729.
  - 31 Bechman, K. – Subesinghe, S. – Norton, S., et al.: A systematic review and meta-analysis of infection risk with small molecule JAK inhibitors in rheumatoid arthritis. *Rheumatology*, 2019, 58, s. 1755–1766.
  - 32 Fleischmann, R. – Kremer, J. – Cush, J., et al.: Placebo-controlled trial of tofacitinib monotherapy in rheumatoid arthritis. *N Engl J Med*, 2012, 367, s. 495–507.
  - 33 Kremer, J. M. – Bloom, B. J. – Breedveld, F. C., et al.: The safety and efficacy of a JAK inhibitor in patients with active rheumatoid arthritis: Results of a double-blind, placebo-controlled phase IIa trial of three dosage levels of CP-690,550 versus placebo. *Arthritis Rheum*, 2009, 60, s. 1895–1905.
  - 34 Kremer, J. – Li, Z. G. – Hall, S. – Fleischmann, R., et al.: Tofacitinib in combination with nonbiologic disease-modifying antirheumatic drugs in patients with active rheumatoid arthritis: a randomized trial. *Ann Intern Med*, 2013, 159, s. 253–261.
  - 35 Chakravarty, E. F. – Michaud, K. – Katz, R., et al.: Increased incidence of herpes zoster among patients with systemic lupus erythematosus. *Lupus*, 2013, 22, s. 238–244.
  - 36 Kim, H. – Cho, S. K. – Lee, J., et al.: Increased risk of opportunistic infection in early rheumatoid arthritis. *Int J Rheum Dis*, 2019, 22, s. 1239–1246.
  - 37 Smitten, A. L. – Choi, H. K. – Hochberg, M. C., et al.: The risk of herpes zoster in patients with rheumatoid arthritis in the United States and the United Kingdom. *Arthritis Rheum*, 2007, 57, s. 1431–1438.
  - 38 van der Heijde, D. – Tanaka, Y. – Fleischmann, R., et al.: Tofacitinib (CP-690,550) in patients with rheumatoid arthritis receiving methotrexate: twelve-month data from a twenty-four-month phase III randomized radiographic study. *Arthritis Rheum*, 2013, 65, s. 559–570.
  - 39 Lee, E. B. – Fleischmann, R. – Hall, S., et al.: Tofacitinib versus methotrexate in rheumatoid arthritis. *N Engl J Med*, 2014, 370, s. 2377–2386.
  - 40 Fleischmann, R. – Myuler, E. – Hall, S., et al.: Efficacy and safety of tofacitinib monotherapy, tofacitinib with methotrexate, and adalimumab with methotrexate in patients with rheumatoid arthritis (ORAL Strategy): a phase 3b/4, double-blind, head-to-head, randomised controlled trial. *Lancet*, 2017, 390, s. 457–468.
  - 41 Dougados, M. – van der Heijde, D. – Chen, Y. C., et al.: Baricitinib in patients with inadequate response or intolerance to conventional synthetic DMARDs: results from the RA-BUILD study. *Ann Rheum Dis*, 2017, 76, s. 88–95.
  - 42 Genovese, M. C. – Kremer, J. – Zamani, O., et al.: Baricitinib in patients with refractory rheumatoid arthritis. *N Engl J Med*, 2016, 374, s. 1243–1252.
  - 43 Fleischmann, R. – Schiff, M. – van der Heijde, D., et al.: Baricitinib, methotrexate, or combination in patients with rheumatoid arthritis and no or limited prior disease-modifying antirheumatic drug treatment. *Arthritis Rheumatol*, 2017, 69, s. 506–517.
  - 44 Taylor, P. C. – Keystone, E. C. – van der Heijde, D., et al.: Baricitinib versus placebo or adalimumab in rheumatoid arthritis. *N Engl J Med*, 2017, 376, s. 652–662.
  - 45 Genovese, M. C. – Smolen, J. S. – Weinblatt, M. E., et al.: Efficacy and safety of ABT-494, a selective JAK-1 inhibitor, in a phase IIb study in patients with rheumatoid arthritis and an inadequate response to methotrexate. *Arthritis Rheumatol*, 2016, 68, s. 2857–2866.
  - 46 Genovese, M. C. – Fleischmann, R. – Combe, B., et al.: Safety and efficacy of upadacitinib in patients with active rheumatoid arthritis refractory to biologic disease-modifying anti-rheumatic drugs (SELECT-BEYOND): a double-blind, randomised controlled phase 3 trial. *Lancet*, 2018, 391, s. 2513–2524.
  - 47 Smolen, J. S. – Pangan, A. L. – Emery, P., et al.: Upadacitinib as monotherapy in patients with active rheumatoid arthritis and inadequate response to methotrexate (SELECT-MONOTHERAPY): a randomised, placebo-controlled, double-blind phase 3 study. *Lancet*, 2019, 393, s. 2303–2311.
  - 48 Wollenhaupt, J. – Lee, E. B. – Curtis, J. R., et al.: Safety and efficacy of tofacitinib for up to 9.5 years in the treatment of rheumatoid arthritis: final results of a global, open-label, long-term extension study. *Arthritis Res Ther*, 2019, 21, s. 89.
  - 49 Zhang, Z. – Deng, W. – Wu, Q. – Sun, L., et al.: Tuberculosis, hepatitis B and herpes zoster in tofacitinib-treated patients with rheumatoid arthritis. *Immunotherapy*, 2019, 11, s. 321–333.
  - 50 Kremer, J. M. – Bingham, C. O. 3rd – Cappelli, L. C., et al.: Postapproval comparative safety study of tofacitinib and biological disease-modifying antirheumatic drugs: 5-year results from a United States-based rheumatoid arthritis registry. *ACR Open Rheumatol*, 2021, 3, s. 173–184.
  - 51 Genovese, M. C. – Smolen, J. S. – Takeuchi, T., et al.: Safety profile of baricitinib for the treatment of rheumatoid arthritis up to 7 years: an updated integrated safety analysis. *Arthritis Rheumatol*, 2020, 72, suppl. 10.
  - 52 Smolen, J. S. – Genovese, M. C. – Takeuchi, T., et al.: Safety profile of baricitinib in patients with active rheumatoid arthritis with over 2 years median time in treatment. *J Rheumatol*, 2019, 46, s. 7–18.
  - 53 Arvin, A. M.: Humoral and cellular immunity to Varicella-Zoster virus: an overview. *J Infect Dis*, 2008, 197, suppl. 2, s. 58–60.
  - 54 O’Shea, J. J. – Kontzias, A. – Yamaoka, K., et al.: Janus kinase inhibitors in autoimmune diseases. *Ann Rheum Dis*, 2013, 72, suppl. 2, s. ii111–ii115.
  - 55 Weinberg, A. – Levin, M. J.: VZV T cell-mediated immunity. *Current Top Microbiol Immunol*, 2010, 342, s. 341–357.
  - 56 van Vollenhoven, R. F. – Tanaka, Y. – Lamba, M., et al.: THU0178 relationship between NK cell count and important safety events in rheumatoid arthritis patients treated with tofacitinib. *Ann Rheum Dis*, 2015, 74, suppl. 2, s. 258–259.
  - 57 Emery, P. – McInnes, I. – Genovese, M., et al.: Characterisation of changes in lymphocyte subsets in baricitinib-treated patients with rheumatoid arthritis in two phase 3 studies. *Ann Rheum Dis*, 2016, 75, suppl. 1, s. A62.
  - 58 Winthrop, K. L.: The emerging safety profile of JAK inhibitors in rheumatic disease. *Nat Rev Rheumatol*, 2017, 13, s. 234–243.
  - 59 Clark, J. D. – Flanagan, M. E. – Telliez, J. B.: Discovery and development of Janus kinase (JAK) inhibitors for inflammatory diseases. *J Med Chem*, 2014, 57, s. 5023–5038.
  - 60 Smolen, J. S. – Landewé, R. – Bijlsma, J., et al.: EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis*, 2017, 76, s. 960–977.
  - 61 van der Heijde, D. – Ramiro, S. – Landewé, R., et al.: 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*, 2017, 76, s. 978–991.
  - 62 Fernandez-Martinez, S. – Cortes, X. – Borrás-Blasco, J., et al.: Effectiveness of a systematic vaccination program in patients with autoimmune inflammatory disease treated with anti-TNF alpha drugs. *Expert Opin Biol Ther*, 2016, 16, s. 1317–1322.
  - 63 Ng, B. – McBain, L. – Grainger, R.: Rheumatologists fail to advise people with RA to get immunised, which matters if you are under 65: an audit in a new Zealand rheumatology service. *N Z Med J*, 2016, 129, s. 72–78.
  - 64 Furur, V. – Rondaan, Ch. – Heijstek, M. W., et al.: 2019 update of EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases. *Ann Rheum Dis*, 2020, 79, s. 39–52.
  - 65 Zhang, J. – Xie, F. – Delzell, E., et al.: Association between vaccination for herpes zoster and risk of herpes zoster infection among older patients with selected immune-mediated diseases. *JAMA*, 2012, 308, s. 43–49.
  - 66 Oxman, M. N. – Levin, M. J. – Johnson, G. R., et al.: A vaccine to prevent herpes zoster and postherpetic neuralgia in older adults. *N Engl J Med*, 2005, 352, s. 2271–2284.
  - 67 Schmader, K. E. – Levin, M. J. – Gnann, J. W., et al.: Efficacy, safety, and tolerability of herpes zoster vaccine in persons aged 50–59 years. *Clin Infect Dis*, 2012, 54, s. 922–928.
  - 68 Friedman, M. A. – Winthrop, K. L.: Vaccines and disease-modifying antirheumatic drugs: practical implications for the rheumatologist. *Rheum Dis Clin North Am*, 2017, 43, s. 1–13.
  - 69 Mahadevan, U. – Wolf, D. C. – Dubinsky, M., et al.: Placental transfer of anti-tumor necrosis factor agents in pregnant patients with inflammatory bowel disease. *Clin Gastroenterol Hepatol*, 2013, 11, s. 286–292.
  - 70 Zelenkova, Z. – de Haar, C. – de Ridder, L., et al.: High intra-uterine exposure to infliximab following maternal anti-TNF treatment during pregnancy. *Aliment Pharmacol Ther*, 2011, 33, s. 1053–1058.
  - 71 Berthelsen, B. G. – Fjeldsøe-Nielsen, H. – Nielsen, C. T., et al.: Etanercept concentrations in maternal serum, umbilical cord serum, breast milk and child serum during breast feeding. *Rheumatology*, 2010, 49, s. 2225–2227.
  - 72 Marra, F. – Parhar, K. – Huang, B., et al.: Risk factors for herpes zoster infection: a meta-analysis. *Open Forum Infect Dis*, 2020, 7, s. ofaa005.
  - 73 Dooling, K. – Guo, A. – Leung, J., et al.: Performance of zoster vaccine live (Zostavax): a systematic review of 12 years of experimental and observational evidence. *Open Forum Infect Dis*, 2017, 4, suppl. 1, s. 412–413.
  - 74 Sly, J. R. – Harris, A. L.: Recombinant zoster vaccine (Shingrix) to prevent herpes zoster. *Nurs Womens Health*, 2018, 22, s. 417–422.
  - 75 Product Monograph Including Patient Medication Information. Shingrix. Herpes Zoster vaccine (non-live recombinant, AS01B adjuvanted). Suspension for injection. Active immunizing agent. GlaxoSmithKline (GSK). Dostupné z: [https://ca.gsk.com/media/1350788/shingrix\\_pm-2017-10-13.pdf](https://ca.gsk.com/media/1350788/shingrix_pm-2017-10-13.pdf), vyhledáno 23. 4. 2019.
  - 76 Baumrin, E. – Van Voorhees, A. – Garg, A., et al.: A systematic review of herpes zoster incidence and consensus recommendations on vaccination in adult patients on systemic therapy for psoriasis or psoriatic arthritis: from the medical Board of the National psoriasis Foundation. *J Am Acad Dermatol*, 2019, 81, s. 102–110.
  - 77 Advisory Committee on Immunization Practices (ACIP). Zoster (Shingles) ACIP Vaccine Recommendations. Dostupné z: <https://www.cdc.gov/vaccines/hcp/aciprecs/vacc-specific/shingles.html>, vyhledáno 24. 2. 2019.
  - 78 Lal, H. – Cunningham, A. L. – Godeaux, O., et al.: Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. *N Engl J Med*, 2015, 372, s. 2087–2096.
  - 79 Cunningham, A. L. – Lal, H. – Kovac, M., et al.: Efficacy of the herpes zoster subunit vaccine in adults 70 years of age or older. *N Engl J Med*, 2016, 375, s. 1019–1032.
  - 80 Tricco, A. C. – Zarin, W. – Cardoso, R., et al.: Efficacy, effectiveness, and safety of herpes zoster vaccines in adults aged 50 and older: systematic review and network meta-analysis. 2018. Dostupné z: <https://www.bmjjournals.org/content/363/bmjj.k4029>, vyhledáno 6. 7. 2021.

## Klasifikační kritéria EULAR/ACR pro systémový lupus erythematoses (2019)

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- 1 Tan, E. M. – Cohen, A. S. – Fries, J. F., et al.: The 1982 revised criteria for the classification of systemic lupus erythematosus. *Arthritis Rheum*, 1982, 25, s. 1271–1277.
- 2 Hochberg, M. C., for the Diagnostic and Therapeutic Criteria

Committee of the American College of Rheumatology: Updating the American College of Rheumatology revised criteria for the classification of systemic lupus erythematosus [letter]. *Arthritis Rheum*, 1997, 40, s. 1725.

- 3 Petri, M. – Orbai, A. M. – Alarcón, G. S., et al.: Derivation and validation of the Systemic Lupus International Collaborating Clinics classification criteria for systemic lupus erythematosus. *Arthritis Rheum*, 2012, 64, s. 2677–2686.

- 4 Aringer, M. – Costenbader, K. – Daikh, D., et al.: European League Against Rheumatism/American College of Rheumatology classification criteria for systemic lupus erythematosus. *Ann Rheum Dis*, 2019, 78, s. 1151–1159.
- 5 Carneiro, A. C. – Ruiz, M. M. – Freitas, S., et al.: A comparison of three classification criteria sets for Systemic Lupus Erythematosus – a study looking at links to outcome and mortality. *Arthritis Care Res*, 2020, 72, s. 1611–1614.
- 6 Adamichou, Ch. – Nikolopoulos, D. – Genitsaridi, I., et al.: In an early SLE cohort the ACR-1997, SLICC-2012 and EULAR/ACR-2019 criteria classify non-overlapping groups of patients: use of all three criteria ensures optimal capture for clinical studies while their modification earlier classification and treatment. *Ann Rheum Dis*, 2020, 79, s. 232–241.

## Léčba vaskulitid velkých tepen – aktualizovaná doporučení EULAR

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- 1 Muhktyar, C. – Guillemin, L. – Cid, M. C., et al.: EULAR recommendations for the management of large vessel vasculitis. *Ann Rheum Dis*, 2009, 68, s. 318–323.
- 2 Hellmich, C. – Agueda, A. – Monti, S., et al.: 2018 Update of the EULAR recommendations for the management of large vessel vasculitis. *Ann Rheum Dis*, 2020, 79, s. 9–30.
- 3 Van der Heijde, D. – Aletaha, D. – Carmona, L., et al.: 2014 update of the EULAR standardized operating procedures for EULAR-endorsed recommendations. *Ann Rheum Dis*, 2015, 74, s. 8–13.
- 4 Luqmani, R. – Lee, E. – Singh, S., et al.: The role of ultrasound compared to biopsy of temporal arteries in the diagnosis and treatment of giant cell arteritis (TABUL): a diagnostic accuracy and cost-effectiveness study. *Health Technol Assess*, 2016, 20, s. 1–238.
- 5 Hauenstein, C. – Reinhard, M. – Geiger, J., et al.: Effects of early corticosteroid treatment on magnetic resonance imaging and ultrasonography findings in giant cell arteritis. *Rheumatology*, 2012, 51, s. 1999–2003.
- 6 Maleszewski, J. J. – Younge, B. R. – Fritzen, J. T., et al.: Clinical and pathological evolution of giant cell arteritis: a prospective study of follow-up temporal artery biopsies in 40 treated patients. *Mod Pathol*, 2017, 30, s. 788–796.
- 7 Blockmans, D. – de Ceuninck, L. – Vanderschueren, S., et al.: Repetitive 18F fluorodeoxyglucose positron emission tomography in giant cell arteritis: a prospective study of 35 patients. *Arthritis Rheum*, 2006, 55, s. 131–137.
- 8 Germano, G. – Muratore, F. – Cimino, L., et al.: Is colour duplex sonography-guided temporal artery biopsy useful in the diagnosis of giant cell arteritis? A randomized study. *Rheumatology*, 2015, 54, s. 400–404.
- 9 Hernández-Rodríguez, J. – Murgia, G. – Villar, I., et al.: Description and validation of histological patterns and proposal of a dynamic model of inflammatory infiltration in giantcell arteritis. *Medicine*, 2016, 95, e2368.
- 10 Breuer, G. S. – Nesher, R. – Reinus, K., et al.: Association between histological features in temporal artery biopsies and clinical features of patients with giant cell arteritis. *Isr Med Assoc J*, 2013, 15, s. 271–274.
- 11 Cavazza, A. – Muratore, F. – Boiardi, L., et al.: Inflamed temporal artery: histologic findings in 354 biopsies, with clinical correlations. *Am J Surg Pathol*, 2014, 38, s. 1360–1370.
- 12 Chatelain, D. – Duhamet, P. – Schmidt, J., et al.: Pathological features of temporal arteries in patients with giant cell arteritis presenting with permanent visual loss. *Ann Rheum Dis*, 2009, 68, s. 84–88.
- 13 Makkuni, D. – Bharadwaj, A. – Wolfe, K., et al.: Is intimal hyperplasia a marker of neuro-ophthalmic complications of giant cell arteritis? *Rheumatology*, 2008, 47, s. 488–490.
- 14 Muratore, F. – Boiardi, L. – Cavazza, A., et al.: Correlations between histopathological findings and clinical manifestations in biopsy-proven giant cell arteritis. *J Autoimmun*, 2016, 69, s. 94–101.
- 15 Restuccia, G. – Boiardi, L. – Cavazza, A., et al.: Flares in biopsy-proven giant cell arteritis in northern Italy: characteristics and predictors in a long-term follow-up study. *Medicine*, 2016, 95, e3524.
- 16 Stone, J. H. – Tuckwell, K. – Dimonaco, S., et al.: Trial of tocilizumab in giantcell arteritis. *N Engl J Med*, 2017, 377, s. 317–328.
- 17 Raine, C. – Stapleton, P. P. – Merinopoulos, D., et al.: A 26-week feasibility study comparing the efficacy and safety of modified-release prednisone with immediate-release prednisolone in newly diagnosed cases of giant cell arteritis. *Int J Rheum Dis*, 2018, 21, s. 285–291.
- 18 Mazlumzadeh, M. – Hunder, G. G. – Easley, K. A., et al.: Treatment of giant cell arteritis using induction therapy with high-dose glucocorticoids: a double-blind, placebo-controlled, randomized prospective clinical trial. *Arthritis Rheum*, 2006, 54, s. 3310–3318.
- 19 Chevalet, P. – Barrier, J. H. – Pottier, P., et al.: A randomized, multicenter, controlled trial using intravenous pulses of methylprednisolone in the initial treatment of simple forms of giant cell arteritis: a one year follow-up study of 164 patients. *J Rheumatol*, 2000, 27, s. 1484–1491.
- 20 Les, I. – Pijoan, J. I. – Rodriguez-Alvarez, R., et al.: Effectiveness and safety of medium-dose prednisone in giant cell arteritis: a retrospective cohort study of 103 patients. *Clin Exp Rheumatol*, 2015, 33, suppl. 89, s. 90–97.
- 21 Buttigereit, F. – da Silva, J. A. P. – Boers, M., et al.: Standardised nomenclature for glucocorticoid dosages and glucocorticoid treatment regimens: current questions and tentative answers in rheumatology. *Ann Rheum Dis*, 2002, 61, s. 718–722.
- 22 Sanden, S. – Tripimacher, R. – Weltrich, R., et al.: Glucocorticoid dose dependent down regulation of glucocorticoid receptors in patients with rheumatic diseases. *J Rheumatol*, 2000, 27, s. 1265–1270.
- 23 Alba, M. A. – García-Martínez, A. – Prieto-González, S., et al.: Relapses in patients with giant cell arteritis: prevalence, characteristics, and associated clinical findings in a longitude finally followed cohort of 106 patients. *Medicine*, 2014, 93, s.194–201.
- 24 Kermani, T. A. – Warrington, K. J. – Cuthbertson, D., et al.: Disease relapses among patients with giant cell arteritis: a prospective, longitudinal cohort study. *J Rheumatol*, 2015, 42, s. 1213–1217.
- 25 Labanca, C. – Koster, M. J. – Crowson, C. S., et al.: Predictors of relapse and treatment outcomes in biopsy-proven giant cell arteritis: a retrospective cohort study. *Rheumatology*, 2016, 55, s. 347–356.
- 26 Nesher, G. – Nesher, R. – Mates, M., et al.: Giant cell arteritis: intensity of the initial systemic inflammatory response and the course of the disease. *Clin Exp Rheumatol*, 2008, 26, 3 suppl. 49, s. 530–534.
- 27 Mahr, A. D. – Jover, J. A. – Spiera, R. F., et al.: Adjuvant methotrexate for treatment of giant cell arteritis: an individual patient data meta-analysis. *Arthritis Rheum*, 2007, 56, s. 2789–2797.
- 28 Rigby, W. F. C. – Lampi, K. – Low, J. M., et al.: Review of routine laboratory monitoring for patients with rheumatoid arthritis receiving biologic or non biologic DMARDs. *Int J Rheumatol*, 2017, 2017, s. 1–15.
- 29 Langford, C. A. – Cuthbertson, D. – Ytterberg, S. R., et al.: A randomized, double-blind trial of abatacept (CTLA-4Ig) for the treatment of giant cell arteritis. *Arthritis Rheumatol*, 2017, 69, s. 837–845.
- 30 Conway, R. – O'Neill, L. – O'Flynn, E., et al.: Ustekinumab for the treatment of refractory giant cell arteritis. *Ann Rheum Dis*, 2016, 75, s. 1578–1579.
- 31 Quartuccio, L. – Maset, M. – De Maglio, G., et al.: Role of oral cyclophosphamide in the treatment of giant cell arteritis. *Rheumatology*, 2012, 51, s. 1677–1686.
- 32 Lock, J. – Henes, J. – Köller, I., et al.: Treatment of refractory giant cell arteritis with cyclophosphamide: a retrospective analysis of 35 patients from three centres. *Clin Exp Rheumatol*, 2012, 30, 1 suppl. 70, s. S70–S76.
- 33 de Boysson, H. – Boutry, J. – Creveuil, C., et al.: Is there a place for cyclophosphamide in the treatment of giant-cell arteritis? A case series and systematic review. *Semin Arthritis Rheum*, 2013, 43, s. 105–112.
- 34 Adzie, T. – Christidis, D. – Dharmapaliah, C., et al.: Efficacy and tolerability of leflunomide in difficult-to-treat polymyalgia rheumatica and giant cell arteritis: a case series. *Int J Clin Pract*, 2012, 66, s. 906–909.
- 35 Hoffman, G. S. – Cid, M. C. – Rendt-Zagar, K. E., et al.: Infliximab for maintenance of glucocorticosteroid-induced remission of giant cell arteritis: a randomized trial. *Ann Intern Med*, 2007, 146, s. 621–630.
- 36 Martínez-Taboada, V. M. – Rodríguez-Valverde, V. – Carreño, L., et al.: A double-blind placebo controlled trial of etanercept in patients with giant cell arteritis and corticosteroid side effects. *Ann Rheum Dis*, 2008, 67, s. 625–630.
- 37 Seror, R. – Baron, G. – Hatchull, E., et al.: Adalimumab for steroid sparing in patients with giant cell arteritis: results of a multicenter randomized controlled trial. *Ann Rheum Dis*, 2014, 73, s. 2074–2081.
- 38 Schaufelberger, C. – Andersson, R. – Nordborg, E.: No additive effect of cyclosporine A compared with glucocorticoid treatment alone in giant cell arteritis: results of an open, controlled, randomized study. *Rheumatology*, 1998, 37, s. 464–465.
- 39 Schaufelberger, C. – Möllby, H. – Uddhammar, A., et al.: No additional steroid-sparing effect of cyclosporine A in giant cell arteritis. *Scand J Rheumatol*, 2000, 35, s. 327–329.
- 40 Ly, K. H. – Dalmay, F. – Gondran, G., et al.: Steroid-sparing effect and toxicity of dapsone treatment in giant cell arteritis: a single-center, retrospective study of 70 patients. *Medicine*, 2016, 95, e4974.
- 41 Ohigashi, H. – Haraguchi, G. – Konishi, M., et al.: Improved prognosis of Takayasu arteritis over the past decade—comprehensive analysis of 106 patients. *Circ J*, 2012, 76, s. 1004–1011.
- 42 Comarmond, C. – Biard, L. – Lambert, M., et al.: Long-term outcomes and prognostic factors of complications in Takayasu arteritis: a multi-center study of 318 patients. *Circulation*, 2017, 136, s. 1114–1122.
- 43 Maksimowicz-McKinnon, K. – Clark, T. M. – Hoffman, G. S.: Limitations of therapy and a guarded prognosis in an American cohort of Takayasu arteritis patients. *Arthritis Rheum*, 2007, 56, s. 1000–1009.
- 44 Bicakçigil, M. – Aksu, K. – Kamali, S., et al.: Takayasu's arteritis in Turkey – clinical and angiographic features of 248 patients. *Clin Exp Rheumatol*, 2009, 27, 1 suppl. 52, s. 559–564.
- 45 Hoffman, G. S. – Leavitt, R. Y. – Kerr, G. S., et al.: Treatment of glucocorticoid-resistant or relapsing Takayasu arteritis with methotrexate. *Arthritis Rheum*, 1994, 37, s. 578–582.
- 46 de Souza, A. W. S. – de Almeida Agustinielli, R. – de Cinque Almeida, H., et al.: Leflunomide in Takayasu arteritis – a long-term observational study. *Rev Bras Reumatol Engl Ed*, 2016, 56, s. 371–375.
- 47 Shinjo, S. K. – Pereira, R. M. R. – Tizzani, V. A. P., et al.: Mycophenolate mofetil reduces disease activity and steroid dosage in Takayasu arteritis. *Clin Rheumatol*, 2007, 26, s. 1871–1875.
- 48 Valsakumar, A. K. – Valappil, U. C. – Jorapur, V., et al.: Role of immunosuppressive therapy on clinical, immunological, and angiographic outcome in active Takayasu's arteritis. *J Rheumatol*, 2003, 30, s. 1793–1798.
- 49 Kermani, T. A. – Schmidt, J. – Crowson, C. S., et al.: Utility of erythrocyte sedimentation rate and C-reactive protein for the diagnosis of giant cell arteritis. *Semin Arthritis Rheum*, 2012, 41, s. 866–871.
- 50 Gonzalez-Gay, M. A. – Vazquez-Rodriguez, T. R. – Gomez-Acebo, I., et al.: Strokes at time of disease diagnosis in a series of 287 patients with biopsy-proven giant cell arteritis. *Medicine*, 2009, 88, s. 227–235.
- 51 Narváez, J. – Bernad, B. – Gómez-Vaquero, C., et al.: Impact of antiplatelet therapy in the development of severe ischemic complications and in the outcome of patients with giant cell arteritis. *Clin Exp Rheumatol*, 2008, 26, 3 suppl. 49, s. 557–562.
- 52 Martínez-Taboada, V. M. – López-Hoyos, M. – Narváez, J., et al.: Effect of antiplatelet/anticoagulant therapy on severe ischemic complications in patients with giant cell arteritis: a cumulative meta-analysis. *Autoimmun Rev*, 2014, 13, s. 788–794.
- 53 Fields, C. E. – Bower, T. C. – Cooper, L. T., et al.: Takayasu's arteritis: operative results and influence of disease activity. *J Vasc Surg*, 2006, 43, s. 64–71.
- 54 Kermani, T. A. – Warrington, K. J. – Crowson, C. S., et al.: Large-vessel involvement in giant cell arteritis: a population-based cohort study of the incidence-trends and prognosis. *Ann Rheum Dis*, 2013, 72, s. 1989–1994.