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Komorbidita u spondyloartritid v národním registru ATTRA pacientů léčených biologickými léky

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

- 1 Coates, L., et al.: Group for research and assessment of psoriasis and psoriatic arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis. *Nat Rev Rheumatol*, 2022, 18, s. 465–479.
- 2 Coates, L., et al.: Group for research and assessment of psoriatic arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis. *Nat Rev Rheumatol*, 2022, 18, s. 465–479.
- 3 Kamalaraj, N., et al.: Systematic review of depression and anxiety in psoriatic arthritis. *Int J Rheum Dis*, 2019, 22, s. 967–973.
- 4 Molto, A., et al.: Prevalence of comorbidities and evaluation of their screening in SpA. Results of the international cross-sectional ASAS COMOSPA study. *Ann Rheum Dis*, 2016, 75, s. 1016–1023.
- 5 Perez-Chada, L., et al.: Comorbidities associated with psoriatic arthritis: review and update. *Clin Immunol*, 2020, 214, s. 1–9.
- 6 Moll, J. M. – Wright, V.: Psoriatic arthritis. *Semin Arthritis Rheum*, 1973, 3, s. 55–78.
- 7 Gupta, S., et al.: Comorbidities in psoriatic arthritis. A systematic review and meta-analysis. *Rheum Intern*, 2021, 41, s. 275–284.
- 8 England, B. R., et al.: Validation of the rheumatic disease comorbidity index. *Arthritis Care Res*, 2015, 67, s. 865–872.
- 9 Nikiphorou, E., et al.: Association of comorbidities in spondyloarthritis with poor function, work disability and quality of life: results from the assessment of spondyloarthritis international society comorbidities in SpA study. *Arthritis Care Res*, 2018, 20, s. 1257–1762.
- 10 Zhao, S., et al.: Prevalence and impact of comorbidities in axial spondyloarthritis: systematic review and meta-analysis. *Rheumatol*, 2020, 59, s. iv47–iv57.
- 11 Bailet, A., et al.: Points to consider for reporting screening for preventin selected comorbidities in chronic inflammatory rheumatic diseases in daily practise. EULAR initiative. *Ann Rheum Dis*, 2016, 75, s. 965–973.
- 12 Boonen, A., et al.: With drawal from labor force due to work disability in patients with ankylosing spondylitis. *Ann Rheum Dis*, 2001, 60, s. 1033–1039.
- 13 Lee, S., et al.: Comorbidity, disability, and healthcare expenditure of AS in Korea: A population-based study. Ramagopalan, S., ed: *PLOS ONE*, 2018, 13, e0192524.
- 14 Coates, L. – Gosse, L.: The updated GRAPPA and EULAR recommendations for the management of psoriatic arthritis: Similarities and differences. *Joint Bone Spine*, 2023, 90, 105469.

Biosimilární tocilizumab v léčbě autoimunitních revmatických onemocnění

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

- 1 Smolen, J. S. – Caporali, R. – Doerner, T., et al.: Treatment journey in rheumatoid arthritis with biosimilars: from better access to good disease control through cost savings and prevention of nocebo effects. *RMD Open*, 2021, 7, e001637.
- 2 Eulenfeld, R., et al.: Interleukin 6 signaling more than JAKs and STATs. *Eur J Cell Biol*, 2012, 91, s. 486–495.
- 3 Jones, G., et al.: Comparison of tocilizumab monotherapy versus MTX monotherapy in patients with moderate to severe RA: AMBITION study. *Ann Rheum Dis*, 2010, 69, s. 88–96.
- 4 Kremer, J. M., et al.: Tocilizumab inhibits structural joint damage in rheumatoid arthritis patients with inadequate responses to MTX: results from the double blind phase of a randomised placebo controlled trial of tocilizumab safety and prevention if structural damage at one year. *Arthritis Rheum*, 2011, 63, s. 609–621.
- 5 Smolen, J. S. – Beaulieu, A. – Rubbert-Roth, A.: Effect of interleukin 6-receptor inhibition with tocilizumab in patients with rheumatoid arthritis (OPTION study): a double blind, placebo controlled, randomised trial. *Lancet*, 2008, 371, s. 987–997.
- 6 Genovese, M. C., et al.: Interleukin-6 receptor inhibition with tocilizumab reduces disease activity in rheumatoid arthritis with inadequate response to DMARDs: tocilizumab combination with traditional disease modifying antirheumatic drug therapy study. *Arthritis Rheum*, 2008, 58, s. 2968–2980.
- 7 Emery, P., et al.: IL-6 receptor inhibition with tocilizumab improves treatment outcomes in patients with rheumatoid arthritis refractory to anti TNF biologicals: results from a 24 week multicentre randomised placebo controlled trial. *Ann Rheum Dis*, 2008, 67, s. 1516–1523.
- 8 Bykerk, V., et al.: Comparison of tocilizumab as monotherapy or with add-on disease-modifying antirheumatic drugs in patients with RA and inadequate responses to previous treatments. An open-label study to clinical practise. *Clin Rheumatol*, 2015, 34, s. 563–571.
- 9 Gabay, C. – Emery, P. – van Vollenhoven, R., et al.: Tocilizumab monotherapy versus adalimumab monotherapy for treatment of rheumatoid arthritis (ADACTA): a randomised, double-blind, controlled phase 4 trial. *Lancet*, 2013, 381, s. 1541–1550.
- 10 Smolen, J.: EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*, 2023, 82, s. 3–180.
- 11 Burmester, G., et al.: Efficacy and safety of subcutaneous tocilizumab versus intravenous tocilizumab in combination with traditional DMARDs in patients with RA at week 97 (SUMMECTA). *Ann Rheum Dis*, 2016, 75, s. 68–74.
- 12 Kivitz, A. – Olech, E. – Borofsky, M., et al.: Subcutaneous tocilizumab versus placebo in combination with disease-modifying antirheumatic drugs in patients with rheumatoid arthritis. *Arthritis Care Res*, 2014, 66, s. 1653–1661.
- 13 Lauper, K. – Nordström, D. C. – Pavelka, K., et al.: Comparative effectiveness of tocilizumab versus TNF inhibitors as monotherapy or in combination with conventional synthetic disease-modifying antirheumatic drugs in patients with rheumatoid arthritis after the use of at least one biologic disease-modifying antirheumatic drug: analyses from the pan-European TOCERRA register collaboration. *Ann Rheum Dis*, 2018, 77, s. 1276–1282.
- 14 Lauper, K., et al.: Oral glucocorticoid use in patients with rheumatoid arthritis initiating TNF-inhibitors, tocilizumab or abatacept: Results from the international TOCERRA and PANABA observational collaborative studies. *Joint Bone Spine*, 2024, 91, 105671.
- 15 Lauper, K. – Mongin, D. – Iannone, F., et al.: Comparative effectiveness of subcutaneous tocilizumab versus intravenous tocilizumab in a pan-European collaboration of registries. *RMD Open*, 2018, 4, e000809.
- 16 Schwabe, C. – Illes, A. – Ullmann, M., et al.: Pharmacokinetics and pharmacodynamics of proposed tocilizumab biosimilar MSB11456 versus both the US-licensed and EU-approved products: a randomized, double-blind trial. *Expert Clin Immunol*, 2022, 18, s. 533–543.
- 17 De Bouer, B. – Huizinga, T. W. J.: Interleukin-6 inhibitors. In: Hochberg, M. C. – Gravallese, E. M. – Smolen, J. S., et al. (ed.): *Rheumatology, 2-Volume Set*. Dostupné z: <https://shop.elsevier.com/books/rheumatology-2-volume-set/hochberg/978-0-7020-8133-0>, vyhledáno 4. 3. 2024.
- 18 Giles, J. R. – Sattar, N. – Gabriel, S. E., et al.: Comparative cardiovascular safety of tocilizumab vs. etanercept in rheumatoid arthritis: results of a randomized, parallel-group, multicenter, non-inferiority, phase 4 clinical trial. *Arthritis Rheumatol*, 2020, 72, s. 31–40.
- 19 Choy, E.: Clinical experience with inhibition of interleukin-6. *Rheum Dis Clin North Am*, 2004, 30, s. 405–415.
- 20 Rose-John, S., et al.: The IL-6/sIL-6R complex as a novel target for therapeutic approaches. *Expert Opin Ther Targets*, 2007, 11, s. 613–624.
- 21 Choy, E. H., et al.: Translating IL-6 biology into effective treatments. *Nat Rev Rheumatol*, 2020, 16, s. 335–345.
- 22 Hoes, J. N. – Jacobs, J. W. G. – Verstappen, S. M. M., et al.: Adverse events of low- to medium-dose oral glucocorticoids in inflammatory diseases: a meta-analysis. *Ann Rheum Dis*, 2009, 68, s. 1833–1838.
- 23 Data on file, F. Hoffmann-La Roche pooled analysis: LITHE, OPTION, TOWARD.
- 24 Data Protection at Fresenius Kabi. Dostupné z: <https://www.fresenius-kabi.com/data-protection>.
- 25 European Medicines Agency. RoActemra (tocilizumab): EPAR – Product Information, 2010. Dostupné z: https://www.ema.europa.eu/en/documents/product-information/roactemra-epar-product-information_en.pdf, vyhledáno 4. 3. 2024.

Bimekizumab – novinky z kongresu EULAR 2024

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- 1 Adams, R. – Maroof, A. – Baker, T., et al.: Bimekizumab, a novel humanized IgG1 antibody that neutralizes both IL-17A and IL-17B. *Front Immunol*, 2020, 11, s. 1894.
- 2 Coates, L. C. – Kristensen, L. E. – Oggie, A., et al.: Bimekizumab-treated patients with active psoriatic arthritis showed sustained achievement of minimal disease activity and remission: up to 2-year results from two phase 3 studies. *Ann Rheum Dis*, 2024, 83, s. 706–707.
- 3 Baraliakos, X. – Deodhar, A. – Van der Heijde, D., et al.: Long-term sustained efficacy and safety of bimekizumab across the full spectrum of axial spondyloarthritis: 2-year results from two phase 3 studies. *Ann Rheum Dis*, 2024, 83, s. 913–914.
- 4 Marzo-Ortega, H. – Mease, P. J. – Dougados, M., et al.: Sustained improvements with bimekizumab in patient-reported symptoms of axial spondyloarthritis: 2-year results from two phase 3 studies. *Ann Rheum Dis*, 2024, 83, s. 912–913.
- 5 Baraliakos, X. – Ramiro, S. – Maksymowich, W. P., et al.: Minimal spinal radiographic progression in patients with radiographic axial spondyloarthritis over 2 years of bimekizumab treatment: results from a phase 3 open-label extension study. *Ann Rheum Dis*, 2024, 83, s. 234.
- 6 Maksymowich, W. P. – Ramiro, S. – Poddubny, D., et al.: Impact of bimekizumab on MRI inflammatory and structural lesions in the sacroiliac joints of patients with axial spondyloarthritis: 52-week results and post hoc analyses from the BE MOBILE 1 and 2 phase 3 studies. *Ann Rheum Dis*, 2024, 83, s. 479–480.

Upadacitinib v úspěšné léčbě anti-TNF indukované vaskulitidy u nemocné s ankylozující spondylitidou – kazuistika

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

- 1 Rudwaleit, M., et al.: The development of ASAS classification kriteria for axialspondyloarthritis (part 2): validation and final selection. *Ann Rheum Dis*, 2009, 68, s. 777–783.
- 2 Zhao, S. S., et al.: Prevalence and impact of comorbidities in axial spondyloarthritis: systematic review and meta-analysis. *Rheumatology*, 2020, 59, s. iv47–57.
- 3 Ramiro, S., et al.: ASAS-EULAR recommendations for the management of axial spondyloarthritis. 2022, update. *Ann Rheum Dis*, 2022, 0, s. 1–16.
- 4 van der Heijde, D., et al.: Efficacy and safety of adalimumab in patients with ankylosing spondylitis: results of multicenter, randomized double blind, placebo controlled trial. *Arthritis Rheum*, 2006, 54, s. 2136–2146.
- 5 Taylor, P., et al.: Tumor necrosis factor inhibitors. In: Hochberg, M., et al.: *Rheumatology*. Elsevier Philadelphia, 2019, s. 553–573.
- 6 Brown, G., et al.: Tumor necrosis factor alpha inhibitor-induced psoriasis: Systematic review of clinical features, histological findings and management experience. *J Am Acad Dermatol*, 2017, 76, s. 334–341.

- 7 Smolen, J., 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.
- 8 Genovese, M., et al.: Safety and efficacy of upadacitinib in patients with active rheumatoid arthritis refractory to biologic disease-modifying antirheumatic drugs (SELECT-Beyond). A double blind, randomised controlled phase 3 trial. *Lancet*, 2018, 391, s. 2513–2524.
- 9 Rubbert-Roth, A., et al.: Trial of upadacitinib or abatacept in rheumatoid arthritis. *N Engl J Med*, 2020, 383, s. 1511–1521.
- 10 van der Heijde, D., et al.: Upadacitinib in active ankylosing spondylitis: results of the 2-year, double-blind, placebo-controlled SELECT-AXIS 1 study and open-label extension. *RMD Open*, 2022, 8, e002280.
- 11 McInnes, I., et al.: Trial of upadacitinib and adalimumab for psoriatic arthritis. *N Engl J Med*, 2021, 384, s. 1127–1239.
- 12 Charles-Schoeman, C., et al.: Risk of major adverse cardiovascular events with tofacitinib versus tumour necrosis factor inhibitors in patients with rheumatoid arthritis with or without a history of atherosclerotic cardiovascular disease: a post hoc analysis from ORAL Surveillance. *An Rheum Dis*, 2023, 82, s. 119–129.
- 13 Fleischmann, R., et al.: Safety profile of upadacitinib in patients at risk of cardiovascular disease: integrated post hoc analysis of the SELECT phase III rheumatoid arthritis clinical programme. *Ann Rheum Dis*, 2023, 82, s. 1–12.
- 14 Šenolt, L., et al.: Doporučené postupy České revmatologické společnosti pro farmakologickou léčbu revmatoidní artritidy – aktualizace v roce 2024. *Česká Revmatol*, 2024, 32, s. 7–24.

Anifrolumab – nová léčebná možnost pro pacienty se systémovým lupus erythematoses

prof. MUDr. Jakub Závada, Ph.D. Revmatologický ústav, Praha

- 1 Morand, E. F. – Furie, R. – Tanaka, Y., et al.: Trial of anifrolumab in active systemic lupus erythematosus. *N Engl J Med*, 2020, 382, s. 211–221.
- 2 Furie, R. A. – Morand, E. F. – Bruce, I. N., et al.: Type I interferon inhibitor anifrolumab in active systemic lupus erythematosus (TULIP-1): a randomised, controlled, phase 3 trial. *Lancet Rheumatol*, 2019, 1, s. e208–e219.
- 3 Furie, R. – Khamashta, M. – Merrill, J. T., et al.: Anifrolumab, an anti-interferon-α receptor monoclonal antibody, in moderate-to-severe systemic lupus erythematosus. *Arthritis Rheumatol*, 2017, 69, s. 376–386.
- 4 Miyazaki, Y. – Funada, M. – Nakayama, S., et al.: Safety and efficacy of anifrolumab therapy in systemic lupus erythematosus in realworld clinical practice: LOOPS registry. *Rheumatology*, 2023, kead568.

Chondroitin sulfát v léčbě symptomatické osteoartrózy

MUDr. Marta Olejárová, Ph.D. Revmatologický ústav a Revmatologická klinika, 1. LF UK, Praha

- 1 Reginster, J.-Y. – Dudler, J. – Blacharski, T. – Pavelka, K.: Pharmaceutical-grade Chondroitin sulfate is as effective as celecoxib and superior to placebo in symptomatic knee osteoarthritis: the ChONDroitin versus CElecoxib versus Placebo Trial (CONCEPT). *Ann Rheum Dis*, 2017, 76, s. 1537–1543.
- 2 Pelletier, J. P. – Raynauld, J. P. – Beaulieu, A. D., et al.: Chondroitin sulfate efficacy versus celecoxib on knee osteoarthritis structural changes using magnetic resonance imaging: a 2-year multicentre exploratory study. *Arthritis Res Ther*, 2016, 18, s. 256.
- 3 Bruyère, O. – Honvo, G. – Veronese, N., et al.: An updated algorithm recommendation for the management of knee osteoarthritis from the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO). *Semin Arthritis Rheum*, 2019, 49, s. 337–350.
- 4 Uebelhart, D. – Thonar, E. J. – Delmas, P. D., et al.: Effects of oral chondroitin sulfate on the progression of knee osteoarthritis: a pilot study. *Osteoarthritis Cartilage*, 1998, suppl. A, s. 39–46.
- 5 Uebelhart, D. – Malaise, M. – Marcolongo, R., et al.: Intermittent treatment of knee osteoarthritis with oral chondroitin sulfate: a one-year, randomized, double-blind, multicenter study versus placebo. *Osteoarthritis Cartilage*, 2004, 12, s. 269–276.
- 6 Kahn, A. – Uebelhart, D. – De Vathaire, F., et al.: Long-term effects of chondroitins 4 and 6 sulfate on knee osteoarthritis: the study on osteoarthritis progression prevention, a two-year, randomized, double-blind, placebo-controlled trial. *Arthritis Rheum*, 2009, 60, s. 524–533.
- 7 Möller, I. – Ahrens, L. – Surm, R., et al.: Distribution and sources of polyfluoroalkyl substances (PFAS) in the River Rhine watershed. *Environmental Pollution*, 2010, 158, s. 3243–3250.
- 8 Michel, B. A. – Stucki, G. – Frey, D., et al.: Chondroitins 4 and 6 sulfate in osteoarthritis of the knee: a randomized, controlled trial. *Arthritis Rheum*, 2005, 52, s. 779–786.
- 9 Runhaar, J., et al.: Response to 'Different glucosamine sulfate products generate different outcomes on osteoarthritis symptoms' by Reginster et al. *Ann Rheum Dis*, 2018, 77, s. e40.
- 10 de Abajo, F. J. – Gil, M. J. – Poza, P. G., et al.: Risk of nonfatal acute myocardial infarction associated with nonsteroidal antiinflammatory drugs, non-narcotic analgesics and other drugs used in osteoarthritis: a nested case-control study. *Pharm Drug Safety*, 2014, DOI: 10.1002/pds.3617.
- 11 Mazzucchelli, R. – Rodríguez-Martín, R. – García-Vadillo, A., et al.: Risk of acute myocardial infarction among new users of chondroitin sulfate: A nested case-control study. *PLoS ONE*, 2021, 16, e0253932.

Secukinumab v léčbě spondyloartritid

MUDr. Kristýna Bubová, Ph.D. Revmatologický ústav a Revmatologická klinika, 1. LF UK, Praha

- 1 Baeten, D. – Sieper, J. – Braun, J., et al.: MEASURE 1 Study Group; MEASURE 2 Study Group: Secukinumab, an interleukin-17A inhibitor, in ankylosing spondylitis. *N Engl J Med*, 2015, 373, s. 2534–2548.
- 2 Braun, J. – Blanco, R. – Marzo-Ortega, H., et al.: Secukinumab in non-radiographic axial spondyloarthritis: subgroup analysis based on key baseline characteristics from a randomized phase III study, PREVENT. *Arthritis Res Ther*, 2021, 23, s. 231.
- 3 Caron, B. – Jouzeau, J. Y. – Miossec, P., et al.: Gastroenterological safety of IL-17 inhibitors: a systematic literature review. *Expert Opin Drug Saf*, 2022, 21, s. 223–239.
- 4 Cua, D. J. – Tato, C. M.: Innate IL-17-producing cells: the sentinels of the immune system. *Nat Rev Immunol*, 2010, 10, s. 479–489.
- 5 Gao, Q. – Zhao, Y. X. – Wang, X. J., et al.: Efficacy and safety of IL-17 inhibitors for patients with psoriatic arthritis: a systematic review and meta-analysis. *Eur Rev Med Pharmacol Sci*, 2021, 25, s. 2958–2970.
- 6 Harrington, L. E. – Hatton, R. D. – Mangan, P. R., et al.: Interleukin 17-producing CD4+ effector T cells develop via a lineage distinct from the T helper type 1 and 2 lineages. *Nat Immunol*, 2005, 6, s. 1123–1132.
- 7 Jancin, B.: Here comes bimekizumab, the newest IL-17 inhibitor. Dostupné z: <https://www.mdedge.com/dermatologynews/article/158562/psoriatic-arthritis/here-comes-bimekizumab-newest-il-17-inhibitor>, vyhledáno 17. 6. 2024.
- 8 Kivitz, A. J. – Nash, P. – Tahir, H., et al.: Efficacy and safety of subcutaneous secukinumab 150 mg with or without loading regimen in psoriatic arthritis: results from the FUTURE 4 study. *Rheumatol Ther*, 2019, 6, s. 393–407.
- 9 McGeachy, M. J. – Cua, D. J. – Gaffen, S. L.: The IL-17 family of cytokines in health and disease. *Immunity*, 2019, 50, s. 892–906.
- 10 McInnes, I. B. – Mease, P. J. – Kirkham, B., et al.: FUTURE 2 Study Group: Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*, 2015, 386, s. 1137–1146.
- 11 Mease, P. – van der Heijde, D. – Landewé, R., et al.: Secukinumab improves active psoriatic arthritis symptoms and inhibits radiographic progression: primary results from the randomised, double-blind, phase III FUTURE 5 study. *Ann Rheum Dis*, 2018, 77, s. 890–897.
- 12 Mease, P. J. – McInnes, I. B. – Kirkham, B.: FUTURE 1 Study Group: Secukinumab inhibition of interleukin-17A in patients with psoriatic arthritis. *N Engl J Med*, 2015, 373, s. 1329–1339.
- 13 Mohy ud-din, N. – Carleton, N. – El-Hachem, S., et al.: 731 De novo inflammatory bowel disease after secukinumab use: a population based analysis: 731 Am J Gastroenterol, 2019, 114, s. S431.
- 14 Nash, P. – Mease, P. J. – McInnes, I. B.: FUTURE 3 study group: Efficacy and safety of secukinumab administration by autoinjector in patients with psoriatic arthritis: results from a randomized, placebo-controlled trial (FUTURE 3). *Arthritis Res Ther*, 2018, 20, s. 47.
- 15 Orrell, K. A. – Murphrey, M. – Kelm, R. C., et al.: Inflammatory bowel disease events after exposure to interleukin 17 inhibitors secukinumab and ixekizumab: post marketing analysis from the RADAR (Research on Adverse Drug Events and Reports) program. *J Am Acad Dermatol*, 2018, 79, s. 777–778.
- 16 Pettipain, N. – D’Amico, F. – Yelehe-Okouma, M., et al.: IL-17 Inhibitors and inflammatory bowel diseases: a postmarketing study in vi-gibase. *Clin Pharmacol Ther*, 2021, 110, s. 159–168.
- 17 Schinocca, C. – Rizzo, C. – Fasano, S., et al.: Role of the IL-23/IL-17 pathway in rheumatic diseases: an overview. *Front Immunol*, 2021, 12, 637829.
- 18 Schreiber, S. – Colombel, J. F. – Feagan, B. G., et al.: Incidence rates of inflammatory bowel disease in patients with psoriasis, psoriatic arthritis and ankylosing spondylitis treated with secukinumab: a retrospective analysis of pooled data from 21 clinical trials. *Ann Rheum Dis*, 2019, 78, s. 473–479.
- 19 Bhatia, A. – Kruglik Cleveland, N. – Gupta, N., et al.: Rapid onset of inflammatory bowel disease after receiving secukinumab infusion. *ACG Case Rep J*, 2018, 5, s. e56.
- 20 Wright, S. – Aloo, A. – Strunk, A., et al.: Real-world risk of new-onset inflammatory bowel disease among patients with psoriasis exposed to interleukin 17 inhibitors. *J Am Acad Dermatol*, 2020, 83, s. 382–387.
- 21 Yamada, A. – Wang, J. – Komaki, Y., et al.: Systematic review with meta-analysis: Risk of new onset IBD with the use of anti-interleukin-17 agents. *Aliment Pharmacol Ther*, 2019, 50, s. 373–385.

Biosimilární etanercept SB4 – nejnovější data z registrů

MUDr. Radka Moravcová Revmatologický ústav, Praha

- 1 Vencovský, J.: Pět let zkoušení s Benepali v reálné klinické praxi. *Acta medicinae*. Reprint, 2022.
- 2 Emery, P. – Vencovský, J. – Sylwestrzak, A., et al.: A phase III randomised, double-blind, parallel-group study comparing SB4 with etanercept reference product in patients with active rheumatoid arthritis despite methotrexate therapy. *Ann Rheum Dis*, 2017, 76, s. 51–57.
- 3 Emery, P. – Vencovský, J. – Sylwestrzak, A., et al.: 52-week results of the phase 3 randomized study comparing SB4 with reference etanercept in patients with active rheumatoid arthritis. *Rheumatology*, 2017, 56, s. 2093–2101.
- 4 Emery, P. – Vencovský, J. – Sylwestrzak, A., et al.: Long-term efficacy and safety in patients with rheumatoid arthritis continuing on SB4 or switching from reference etanercept to SB4. *Ann Rheum Dis*, 2017, 76, s. 1986–1991.

- 5 **Glintborg, B.** – **Loft, A. G.** – **Omerović, E.**, et al.: To switch or not to switch: results of a nationwide guideline of mandatory switching from originator to biosimilar etanercept. One-year treatment outcomes in 2061 patients with inflammatory arthritis from the DANBIO registry. *Ann Rheum Dis*, 2019, 78, s. 192–200.
- 6 **Giuseppe, D.** – **Lindstrom, U.** – **Bower, H.**, et al.: Comparison of treatment retention of originator vs biosimilar products in clinical rheumatology practice in Sweden. *Rheumatology*, 2022, 61, s. 3596–3605.
- 7 **Larid, G.** – **Baudens, G.** – **Dandurand, A.**, et al.: Differential retention of adalimumab and etanercept biosimilars compared to originator treatments: Results of a retrospective French multicenter study. *Front Med*, 2022, 9, 989514.
- 8 **Haugeberg, G.** – **Bakland, G.** – **Rødevand, E.**, et al.: Effectiveness and persistence in SB4- and reference etanercept treated rheumatoid arthritis patients in ordinary clinical practice in Norway. *Arthritis Care Res*, 2023, 75, s. 1986–1995.
- 9 **Girolomoni, G.** – **Feldman, S. R.** – **Emery, P.**: Comparison of injection-site reactions between the etanercept biosimilar SB4 and the reference etanercept in patients with rheumatoid arthritis from a phase III study. *Br J Dermatol*, 2018, 178, s. 215–216.
- 10 **Emery, P.** – **Vencovsky, J.** – **Sylwestrzak, A.**, et al.: A phase III randomised, double-blind, parallel-group study comparing SB4 with etanercept reference product in patients with active rheumatoid arthritis despite methotrexate therapy. *Ann Rheum Dis*, 2017, 76, s. 51–57.
- 11 **Vieland, N. D.** – **Gardarsdottir, H.** – **Bouvy, M. L.**, et al.: The majority of patients do not store their biologic disease-modifying antirheumatic drugs within the recommended temperature range. *Rheumatology*, 2016, 55, s. 704–709.
- 12 **Kremidas, D.** – **Wisniewski, T.** – **Divino, V. M.**, et al.: Administration burden associated with recombinant human growth hormone treatment: perspectives of patients and caregivers. *J Pediatr Nurs*, 2013, 28, s. 55–63.
- 13 Benepali. Souhrn údajů o přípravku (SPC). Dostupné z: <https://www.ema.europa.eu/en>. Poslední aktualizace: leden 2023.
- 14 **Liao, H.** – **Zhong, Z.** – **Liu, Z.**, et al.: Comparison of the risk of infections in different anti-TNF agents: a meta-analysis. *Int J Rheum Dis*, 2017, 20, s. 161–168.

Metamizol v léčbě bolesti

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- 1 **Rozsivalová, P.** – **Stichhauer, R.** – **Holická, L.**, et al.: Metamizol v léčbě bolesti u pediatrické populace. *Pediatrie pro praxi*, 2020, 21, s. 323–329.
- 2 **Stromer, W.** – **Palladini, M.**: Metamizole: a comprehensive approach to its benefit-risk profile. *EFSM*, 2022, 2, 220153.
- 3 **Moore, R. A.** – **Wiffen, P. J.** – **Derry, S.**, et al.: Non-prescription (OTC) oral analgesics for acute pain – an overview of Cochrane reviews. *Cochrane Database Syst Rev*, 2015, 2015, CD010794.
- 4 SPC Novalgin. Dostupné z: www.sukl.cz.
- 5 The Oxford League Table of Analgesic Efficacy. Dostupné z: <https://images.app.goo.gl/Mnc9ZpZ3CQ7xth66>, vyhledáno 14. 8. 2024.
- 6 **Šimíček, M.**: Oxforská liga analgetik a terapie akutní bolesti z pohledu farmaceuta. *Praktické lékařství*, 2015, 5, s. 54–58.

Účinnost a bezpečnost tofacitinibu v léčbě juvenilní idiopatické artritidy

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- 1 **Brunner, H. I.** – **Schanberg, L. E.** – **Kimura, Y.**, et al.: New medications are needed for children with juvenile idiopathic arthritis. *Arthritis Rheumatol*, 2020, 72, s. 1945–1951.
- 2 **Ruperto, N.** – **Brunner, H. I.** – **Zuber, Z.**, et al.: Pharmacokinetic and safety profile of tofacitinib in children with polyarticular course juvenile idiopathic arthritis: results of a phase 1, open-label, multicenter study. *Pediatr Rheumatol Online J*, 2017, 15, s. 86.
- 3 **Ruperto, N.** – **Brunner, H. I.** – **Synoverska, O.**, et al.: Tofacitinib in juvenile idiopathic arthritis: a double-blind, placebo-controlled, withdrawal phase 3 randomised trial. *Lancet*, 2021, 398, s. 1984–1996.
- 4 **Brunner, H. I.** – **Akikusa, J. D.** – **Al-Abadi, E.**, et al.: Safety and efficacy of tofacitinib for the treatment of patients with juvenile idiopathic arthritis: preliminary results of an open-label, long-term extension study. *Ann Rheum Dis*, 7. 6. 2024, dostupné z: <https://doi.org/10.1136/ard-2023-225094>, vyhledáno 22. 7. 2024.

Stratifikace rizik u nemocných s psoriatickou artritidou a ankylozující spondylitidou léčených tofacitinibem

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- 1 **Ytterberg, S. R.** – **Bhatt, D. L.** – **Mikuls, T. R.**, et al.: Cardiovascular and cancer risk with tofacitinib versus tumor necrosis factor inhibitors in cardiovascular risk-enriched rheumatoid arthritis patients. *Arthritis Rheumatol*, 13. 3. 2024, doi: 10.1002/art.42846.
- 2 **Charles-Schoeman, C.** – **Fleischmann, R.** – **Mysler, E.**, et al.: Risk of venous thromboembolism with tofacitinib versus tumor necrosis factor inhibitors in cardiovascular risk-enriched rheumatoid arthritis patients. *Arthritis Rheumatol*, 2021, 73, suppl. 9, 0958.
- 3 **Charles-Schoeman, C.** – **Buch, M.** – **Dougados, M.**, et al.: Risk factors for major adverse cardiovascular events in patients aged 50 years with RA and C 5 additional cardiovascular risk factor: results from a phase 3b/4 randomised safety study of tofacitinib vs. TNF inhibitors [abstract]. *Arthritis Rheumatol*, 2021, 73, suppl. 9, 0958.
- 4 **Curtis, J. R.** – **Yamaoka, K.** – **Chen, Y. H.**, et al.: Malignancy risk with tofacitinib versus TNF inhibitors in rheumatoid arthritis: results from the open-label, randomised controlled ORAL Surveillance trial. *Ann Rheum Dis*, 2023, 82, s. 331–343.
- 5 **Kristensen, L. E.** – **Danese, S.** – **Yndestad, A.**, et al.: Identification of two tofacitinib subpopulations with different relative risk versus TNF inhibitors: an analysis of the open label, randomised controlled study ORAL Surveillance. *Ann Rheum Dis*, 2023, 82, s. 901–910.
- 6 **Charles-Schoeman, C.** – **Buch, M. H.** – **Dougados, M.**, et al.: Risk of major adverse cardiovascular events with tofacitinib versus tumour necrosis factor inhibitors in patients with rheumatoid arthritis with or without a history of atherosclerotic cardiovascular disease: a post hoc analysis from ORAL Surveillance. *Ann Rheum Dis*, 2023, 82, s. 119–129.
- 7 **Burmester, G. R.** – **Nash, P.** – **Sands, B. E.**, et al.: Adverse events of special interest in clinical trials of rheumatoid arthritis, psoriatic arthritis, ulcerative colitis and psoriasis with 37 066 patient-years of tofacitinib exposure. *RMD Open*, 2021, 7, e001595.
- 8 **Kristensen, L. E.** – **Deodhar, A.** – **Leung, Y. Y.**, et al.: Risk stratification of patients with psoriatic arthritis and ankylosing spondylitis for treatment with tofacitinib: a review of current clinical data. *Rheumatol Ther*, 2024, 11, s. 487–499.
- 9 **Gladman, D.** – **Rigby, W.** – **Azevedo, V. F.**, et al.: Tofacitinib for psoriatic arthritis in patients with an inadequate response to TNF inhibitors. *N Engl J Med*, 2017, 377, s. 1525–1536.
- 10 **Mease, P.** – **Hall, S.** – **FitzGerald, O.**, et al.: Tofacitinib or adalimumab versus placebo for psoriatic arthritis. *N Engl J Med*, 2017, 377, s. 1537–1550.
- 11 **Deodhar, A.** – **Sliwinska-Stanczyk, P.** – **Xu, H.**, et al.: Tofacitinib for the treatment of ankylosing spondylitis: a phase III, randomised, double-blind, placebo-controlled study. *Ann Rheum Dis*, 2021, 80, s. 1004–1013.
- 12 **Karpouzas, G. A.** – **Székely, Z.** – **Baecklund, E.**, et al.: Rheumatoid arthritis disease activity and adverse events in patients receiving tofacitinib or tumor necrosis factor inhibitors: a post hoc analysis of ORAL Surveillance. *Ther Adv Musculoskelet Dis*, 2023, 15, 1759720X231201047.
- 13 **Agca, R.** – **Heslinga, S. C.** – **Rollestad, S.**, et al.: EULAR recommendations for cardiovascular disease risk management in patients with rheumatoid arthritis and other forms of inflammatory joint disorders: 2015/2016 update. *Ann Rheum Dis*, 2017, 76, s. 17–28.

Efekt ixekizumabu na psoriatickou artritidu s axiálními projevy

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- 1 **Yap, K. S.** – **Ye, J. Y.** – **Li, S.**, et al.: Back pain in psoriatic arthritis: defining prevalence, characteristics and performance of inflammatory back pain criteria in psoriatic arthritis. *Ann Rheum Dis*, 2018, 77, s. 1573–1577.
- 2 **Feld, J.** – **Chandran, V.** – **Haroon, N.** – **Inman, R.**, et al.: Axial disease in psoriatic arthritis and ankylosing spondylitis: a critical comparison. *Nat Rev Rheumatol*, 2018, 14, s. 363–371.
- 3 **Feld, J.**, et al.: Is axial psoriatic arthritis distinct from ankylosing spondylitis with and without concomitant psoriasis? *Rheumatology*, 2020, 59, s. 1340–1346.
- 4 **Chandran, V.** – **Toluso, D. C.** – **Cook, R. J.**, et al.: Risk factors for axial inflammatory arthritis in patients with psoriatic arthritis. *J Rheumatol*, 2010, 37, s. 809–815.
- 5 **Mease, P. J.**, et al.: Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. *J Am Acad Dermatol*, 2013, 69, s. 729–735.
- 6 **Poddubnyy, D.** – **Jadon, D. R.** – **Van den Bosch, F.**, et al.: Axial involvement in psoriatic arthritis: An update for rheumatologists. *Semi Arthritis Rheum*, 2021, 51, s. 880–887.
- 7 **Moltó, A.** – **Dougados, M.**: Comorbidities in spondyloarthritis including psoriatic arthritis. *Best Pract Res Clin Rheumatol*, 2018, 32, s. 390–400.
- 8 **Fraga, N. A.** – **Oliveira Mde, F.** – **Follador, I.**, et al.: Psoriasis and uveitis: a literature review. *An Bras Dermatol*, 2012, 87, s. 877–883.
- 9 **Poddubnyy, D.**, et al.: Axial Involvement in Psoriatic Arthritis cohort (AXIS): the protocol of a joint project of the Assessment of SpondyloArthritis international Society (ASAS) and the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA). *Ther Adv Musculoskelet Dis*, 2021, 13, 1759720X211057975.
- 10 **Baraliakos, X.**, et al.: Secukinumab in patients with psoriatic arthritis and axial manifestations: results from the double-blind, randomised, phase 3 MAXIMISE trial. *Ann Rheum Dis*, 2021, 80, s. 582–590.
- 11 **Ramiro, S.**, et al.: ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis*, 2023, 82, s. 19–34.
- 12 **Gossec, L.**, et al.: EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis*, 2024, 83, s. 706–719.
- 13 **Raychaudhuri, S. P.** – **Raychaudhuri, S. K.**: Mechanistic rationales for targeting interleukin-17A in spondyloarthritis. *Arthritis Res Ther*, 2017, 19, s. 51.
- 14 **Dougados, M.**, et al.: Efficacy and safety of ixekizumab through 52 weeks in two phase 3, randomised, controlled clinical trials in patients with active radiographic axial spondyloarthritis (COAST-V and COAST-W). *Ann Rheum Dis*, 2020, 79, s. 176–185.
- 15 **van der Heijde, D.**, et al.: Efficacy and safety of ixekizumab in patients with active psoriatic arthritis: 52-week results from a phase III study (SPIRIT-P1). *J Rheumatol*, 2018, 45, s. 367–377.
- 16 **Smolen, J. S.**, 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.
- 17 **Smolen, J. S.**, et al.: Efficacy and safety of ixekizumab with or without methotrexate in biologic-naïve patients with psoriatic arthritis: 52-week results from SPIRIT-H2H study. *Rheumatol Ther*, 2020, 7, s. 1021–1035.

- 18 Deodhar, A., et al.: Ixekizumab for patients with non-radiographic axial spondyloarthritis (COAST-X): a randomised, placebo-controlled trial. *Lancet*, 2020, 395, s. 53–64.
- 19 Chandran, V., et al.: Ixekizumab treatment of biologic-naïve patients with active psoriatic arthritis: 3-year results from a phase III clinical trial (SPIRIT-P1). *Rheumatology*, 2020, 59, s. 2774–2784.
- 20 Coates, L. C., et al.: Ixekizumab efficacy and safety with and without concomitant conventional disease-modifying antirheumatic drugs (cDMARDs) in biologic DMARD (bDMARD)-naïve patients with active psoriatic arthritis (PsA): results from SPIRIT-P1. *RMD Open*, 2017, 3, e000567.
- 21 Nash, P., 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 phase 3 trial. *Lancet*, 2017, 389, s. 2317–2327.
- 22 Orbai, A. M., et al.: Efficacy and safety of ixekizumab in patients with psoriatic arthritis and inadequate response to TNF inhibitors: 3-year follow-up (SPIRIT-P2). *Rheumatol Ther*, 2021, 8, s. 199–217.
- 23 Genovese, M. C., et al.: Safety and efficacy of ixekizumab in patients with PsA and previous inadequate response to TNF inhibitors: week 52 results from SPIRIT-P2. *Rheumatol*, 2018, 57, s. 2001–2011.
- 24 Coates, L. C. – Helliwell, P. S.: Defining low disease activity states in psoriatic arthritis using novel composite disease instruments. *J Rheumatol*, 2016, 43, s. 371–375.
- 25 Mease, P. J., 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.
- 26 van der Heijde, D., 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.
- 27 van der Heijde, D., et al.: Spinal radiographic progression and predictors of progression in patients with radiographic axial spondyloarthritis receiving ixekizumab over 2 years. *J Rheumatol*, 2022, 49, s. 265–273.
- 28 Braun, J., et al.: Effect of secukinumab on clinical and radiographic outcomes in ankylosing spondylitis: 2-year results from the randomised phase III MEASURE 1 study. *Ann Rheum Dis*, 2017, 76, s. 1070–1077.
- 29 Deodhar, A., et al.: Long-term safety and efficacy of ixekizumab in patients with axial spondyloarthritis: 3-year data from the COAST program. *J Rheumatol*, 2023, 50, s. 1020–1028.

Profil zdravotnického prostředku Prostrolane

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- 1 Rutjes, A. W. – Jüni, P. – da Costa, B. R., et al.: Viscosupplementation for osteoarthritis of the knee: a systematic review and meta-analysis. *Ann Intern Med*, 2012, 157, s. 180–191.
- 2 Bellamy, N. – Campbell, J. – Robinson, V., et al.: Viscosupplementation for the treatment of osteoarthritis of the knee. *Cochrane Database Syst Rev*, 2006, 2006, CD005321.
- 3 Johal, H. – Devji, T. – Schemitsch, E. H., et al.: Viscosupplementation in knee osteoarthritis: evidence revisited. *JBJS Rev*, 2016, 4, s. e11–e111.
- 4 Altman, R. D. – Bedi, A. – Karlsson, J., et al.: Product differences in intra-articular hyaluronic acids for osteoarthritis of the knee. *Am J Sports Med*, 2016, 44, s. 2158–2165.
- 5 Altman, R. – Hackel, J. – Niazi, F., et al.: Efficacy and safety of repeated courses of hyaluronic acid injections for knee osteoarthritis: A systematic review. *Semin Arthritis Rheum*, 2018, 48, s. 168–175.
- 6 Nicholls, M. – Shaw, P. – Niazi, F., et al.: The impact of excluding patients with end-stage knee disease in intra-articular hyaluronic acid trials: a systematic review and meta-analysis. *Adv Ther*, 2019, 36, s. 147–161.
- 7 Cugat, R. – Cuscó, X. – Seijas, R., et al.: Biologic enhancement of cartilage repair: the role of platelet-rich plasma and other commercially available growth factors. *Arthroscopy*, 2015, 31, s. 777–783.
- 8 Filardo, G. – Di Matteo, B. – Di Martino, A., et al.: Platelet-rich plasma intra-articular knee injections show no superiority versus viscosupplementation: a randomized controlled trial. *Am J Sports Med*, 2015, 43, s. 1575–1582.
- 9 Akgül, Y. – Fügen, O.: Recent advances towards the rational design of peptide drugs. *Ankara Ecz Fak Derg J Fac Pharm*, 2004, 33, s. 157–181.
- 10 Agarwal, P. – Rupenthal, I. D.: Injectable implants for the sustained release of protein and peptide drugs. *Drug Discov Today*, 2013, 18, s. 337–349.
- 11 Kesiktaş, F. N. – Dernek, B. – Sen, E. I., et al.: Comparison of the short-term results of single-dose intra-articular peptide with hyaluronic acid and platelet-rich plasma injections in knee osteoarthritis: a randomized study. *Clin Rheumatol*, 2020, 39, s. 3057–3064.