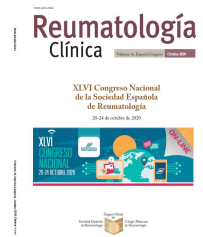




Reumatología Clínica

<https://www.reumatologiaclinica.org>



RC002 - Effect of Sarilumab on Glycosylated Hemoglobin in Patients with Rheumatoid Arthritis and Diabetes

M.E. Pombo Suárez¹, G.R. Burmester², O. Hagino³, H. van Hoogstraten³, E. Mangan⁴, K. Thangavelu⁵, R. Fleischmann⁶ y T. Mandrup-Poulsen⁷

¹Hospital Clínico Universitario de Santiago. Santiago de Compostela. ²Charité-Universitätsmedizin Berlin. Berlin (Germany). ³Sanofi. Bridgewater, NJ (EEUU). ⁴Regeneron Pharmaceuticals, Inc., Tarrytown, NY (EEUU). ⁵Sanofi Genzyme. Cambridge, MA (EEUU). ⁶Metroplex Clinical Research Center. University of Texas Southwestern Medical Center. Dallas, TX (EEUU). ⁷University of Copenhagen. Copenhagen (Denmark).

Resumen

Objectives: Sarilumab, a human monoclonal antibody blocking the interleukin-6 (IL-6) receptor α , is approved for adult patients with moderately to severely active rheumatoid arthritis (RA). Type 2 diabetes is a common comorbidity in patients with RA, and elevated IL-6 may be a risk factor. This post hoc analysis investigated effects of sarilumab on glycosylated hemoglobin (HbA1c) and fasting glucose.

Methods: TARGET (NCT01709578) was a 24-week trial of sarilumab 150/200 mg every two weeks (q2w) vs placebo (all + conventional synthetic disease-modifying antirheumatic drugs (DMARDs)) in tumor necrosis factor inhibitor-inadequate response/intolerant patients; 67/546 (12.3%) patients had diabetes (a medical history of diabetes or concomitant use of antidiabetic treatment). MONARCH (NCT02332590) was a 24-week monotherapy trial of sarilumab 200 mg q2w vs adalimumab 40 mg q2w in methotrexate inadequate response/intolerant, biological DMARD-naïve patients; 26/369 (7.0%) patients had diabetes.

Results: At Week 24, among patients with RA and diabetes, least-squares mean change from baseline in HbA1c was -0.24% / -0.44% with sarilumab 150/200 mg q2w vs $+0.23\%$ with placebo in the combination study and -0.28% vs $+0.15\%$ with sarilumab 200 mg q2w vs adalimumab 40 mg q2w monotherapy. There was no interaction between change in HbA1c and baseline glucocorticoid use, nor were changes in HbA1c correlated with changes in C-reactive protein (CRP), Disease Activity Score 28-CRP, or hemoglobin. Sarilumab-treated patients with baseline IL-6 > 37.5 pg/mL ($> 3 \times$ upper limit of normal) had greater reductions in HbA1c than those with baseline IL-6 ≤ 37.5 pg/mL (least-squares mean change, -0.27% vs -0.13%). Sarilumab safety profile was similar in diabetic vs non-diabetic RA patients.

Conclusions: Patients with RA and diabetes treated with sarilumab had greater improvements in HbA1c than with adalimumab or placebo. With monotherapy, differences between sarilumab and adalimumab were more pronounced among patients with higher baseline IL-6 levels.

Código EUDRACT: NCT02332590.