Effectiveness and safety of original and biosimilar etanercept (Enbrel vs Benepali) in bDMARD-naïve patients in a real-world cohort of Portugal

Biologic agents are an important therapeutic option in the treatment of patients with rheumatic diseases. Etanercept is one of the most widely used biologic disease-modifying anti-rheumatic drug (bDMARD), being approved in diverse indications, including rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (SpA), plaque psoriasis and paediatric plaque psoriasis [2].

The patent expiration of the original etanercept in Europe has facilitated the development of biosimilar products, creating the prospect of reduced treatment costs. In 2016, Benepali became the first etanercept biosimilar to obtain marketing authorization in Europe. A biosimilar is required by the European Medicines Agency and the Food and Drug Administration to demonstrate similarity to the original product in terms of quality characteristics and biological activity. Furthermore, it must demonstrate comparable safety and effectiveness [3,4].

However, subtle differences in efficacy and safety outcomes have been noted and the potential clinical implications for this in daily practice are not established. The ability to extrapolate license indications without data supporting the use of that product in certain indications may create doubt. On-going vigilance by physicians in reporting adverse events and treatment outcomes is consequently essential[1,3,4].

In our study, we intend to compare the effectiveness and safety of the original etanercept (Enbrel) and biosimilar (Benepali) in bDMARD-naïve patients. This study with real-world data can bring more confidence to the physician to choose the best option for the patient, with all the knowledge of the safety and efficacy of the drug.

We hypothesize that the etanercept biosimilar (Benepali) has similar effectiveness and safety profile compared to reference etanercept (Enbrel) in patients with active RA and SpA (axial SpA, peripheral SpA and PsA) in a real-world Portuguese cohort. Our primary aim is to compare the effectiveness and safety of original and biosimilar etanercept, in bDMARD-naïve patients, measured by persistence rates over 4 years of follow-up.

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