

“Persistence in treatment with TNF-alpha inhibitors in Spondyloarthritis: comparison between original and biosimilar drugs - a pilot study”

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Abstract

Biosimilars have demonstrated comparable efficacy, safety and immunogenicity to original drugs in randomized clinical trials, with subsequent extrapolation of their therapeutic indications to those of the original drug. Some studies with real-world data supporting this biosimilarity have been published. However, long-term data on their use in Spondyloarthritis (SpA), particularly regarding persistence beyond 52 weeks, remain scarce.

In an exploratory analysis of 127 patients with SpA followed in our department, we observed a significantly higher persistence rate at 3-years under original TNF-alpha inhibitors (iTNF) (61.4%), with an average drug use time of 27.2 months; compared to 33.3% under biosimilar iTNF, with an average drug use time of 23.7 months ($p=0.012$). The main cause of treatment discontinuation was secondary failure, with a higher proportion observed under biosimilar iTNF (52.8% vs 18.1%, $p<0.01$), with no differences found regarding the rate of AEs. These results suggest greater efficacy of the original iTNF, with no significant differences observed in the safety profile, compared to biosimilars. However, the number of missing data and the relatively small sample size were a limitation of the study, which limits the extrapolation of our conclusions.

The aim of this study is to further evaluate the therapeutic persistence of the original iTNF (Humira[®], Enbrel[®], Simponi[®]) compared to biosimilar agents (Amgevita[®], Hulio[®], Hyrimoz[®], Idacio[®], Imraldi[®], Yuflima[®], Benepali[®], Erelzi[®]) in a larger cohort of patients, as a measure of their medium- and long-term efficacy and safety. Additionally, this study also aims to compare disease activity rates between the groups at 6, 12, 24 and 36 months of therapy, assess the reasons for discontinuation and compare the frequency and severity of adverse events.

