

7th European Biosimilars Congress

May 15-16, 2017 Munich, Germany

Inflectra-our experience on immunogenicity (case series)

Rodica Olteanu, Alexandra Zota and Magda Constantin
Colentina Clinical Hospital, Romania

Biosimilars represent a new tendency in the treatment of many immune-mediated inflammatory diseases, including psoriasis. Regulatory requirements for approval of biosimilars are different from those of originators and rely mostly upon the evidence generated from bioequivalence studies and in particular from RCT, as an important part of it. In our study, case series, we tried to correlate the immunogenicity (measured with ELISA method: Antidrug antibodies and drug level) on 8 patients on Inflectra (infliximab biosimilar), treated more than 8 months in our Dermatology Clinic. Our goal was to determine the evolution of the inflammatory markers (ESR, PCR) together with the evolution of PASI, PASI50 and PASI 90 in a case series of 8 patients for 8 month. We were also capable of evaluating the possible correlations between these indices and immunogenicity. We found an interesting fact that from these 8 patients, 2 had sub-therapeutically drugged level but not anti-infliximab antibodies. One of these 2 patients had also elevated inflammatory markers and the other one has gained more than 10 kg. It was also observed that the third patient developed anti-infliximab-antibodies as well as sub-therapeutically trough level of infliximab. Two months later we evaluated the same parameters and we found no anti-infliximab antibodies. There are some discussions in the literature regarding the transient anti-drug antibodies and therefore the need to repeat them when positive and mainly when the clinical appearance does not explain the paraclinical findings. Our study concluded that, even on small clinical trial you can find valuable information that can help to tailor the treatment for the patient.

Biography

Rodica Olteanu is a Dermatologist and Medical Director of Colentina Clinical Hospital, Bucharest, Romania. She received her PhD in 2007 from Hamburg University. She is involved in autoimmunity and immunogenicity of biologics and biosimilars. She has published more than 100 papers related to lupus and psoriasis. She is the winner of many international grants, member in EADV Project Committee, AAD, GRAPPA, EuSCLC, SRD and ILDS. She completed her educational training from Barcelona and has also visited many institutes as an Invited Speaker.

rodicaolteanu@hotmail.com

Notes: