Severe Infections in Portuguese Patients with Rheumatoid Arthritis Under Biologic Treatment (SIPPRA-B Study)

The therapies used in rheumatoid arthritis, due to their immunomodulatory and immunosuppressive character, carry an infectious risk, which is important in terms of morbidity and mortality in this population. Biological disease-modifying antirheumatic drugs (bDMARDs) have revolutionized the treatment of immune-mediated rheumatic pathology and are, in most patients, a safe and effective therapeutic strategy; however, according to the literature, it seems to increase the risk of severe infections (the most consensual definition of serious infection is the one that leads to the need for hospitalization, due to the severity of the clinical condition and/or need for treatment with intravenous antibiotics, or death), when compared to other therapies [namely, the conventional synthetic DMARDs (csDMARDs)]. Some known predictors of severe infection are age, previous comorbidities, higher disease activity and degree of immunosuppression. Despite years of experience with bDMARDs, studies have elicited controverse reports regarding the infectious risk compared between different bDMARDs, with different mechanisms of action.

As there are not currently national data regarding severe infections under different bDMARDs in Portuguese patients with rheumatoid arthritis, the main objectives of this study are to compare the incidence and site of severe infections in these patients and determine possible predictors for severe infection in our population, hence becoming the first study to demonstrate national data on these topics.

This is a multicenter retrospective cohort study, including patients registered at Reuma.pt with the diagnosis of rheumatoid arthritis (RA) exposed to at least one bDMARD until 30th April 2021; patients with events defined as those with at least one report of serious infection under bDMARD as an adverse event until 30th April 2021. Demographic and clinical data at baseline and at the time of each severe infection will be collected to establish comparisons between different groups of bDMARDs, and will be compared with data at the last evaluation for those who never experienced a serious infection under a bDMARD.

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