Comparative effectiveness and safety of switching to an alternative TNFi or a biologic with a different mode of action (MoA) in Psoriatic Arthritis patients after discontinuation of a first line TNFi: results from the Rheumatic Diseases Portuguese Register

Background:

Psoriatic arthritis (PsA) is a heterogeneous chronic inflammatory rheumatic disease characterized by a wide spectrum of articular and extra-articular manifestations. Tumour necrosis factor alfa inhibitors (TNFi) dramatically improved the treatment of PsA, yet, a significant proportion of patients have an inadequate response and/or are intolerant to a first TNFi, requiring drug discontinuation and switching to other treatment options. After an inadequate response to a first TNFi, in a treat-to-target strategy, the patient may receive a second TNFi (cycling) or a drug with a different mode of action (MoA) – swapping. However, data about the comparative effectiveness of different switching strategies (cycling VS swapping) in clinical daily practice are scarce.

Main objective: To compare the effectiveness and safety of switching to secukinumab or ustekinumab , versus a second TNFi measured by retention rates during a 2 year period of follow-up, in PsA patients with previous inadequate response to their first TNFi.

Methods: This is a retrospective longitudinal cohort study with a 2 -year period of follow-up using a real-world anonymous patient-level data from the Reuma.pt database. Patients registered in Reuma.pt with diagnosis of PsA, fulfilling the classification criteria for PsA (CASPAR) and previous treatment failure to a first-line TNFi that started a second biotechnological (TNFi, secukinumab or ustekinumab) treatment will be included. Baseline sociodemographic data, disease characteristics, disease activity scores, physical function and specific disease therapies (namely concomitant csDMARDs) will be used. We also will use data from follow-up visits at 6,12 and 24 months after starting the second biologic. The data that will be used from the follow-up visits will be: treatment Disease activity scores, physical function, adverse events, biological treatment stopping (yes/no), reasons for stopping the biological treatment (inefficacy, adverse event, remission, other) and pPASQAL, axPASQAL. Persistency of secukinumab/ustekinumab, and TNFi will be estimated using Kaplan-Meier analysis, where follow-up time will be calculated as time in months from initiation of each therapy until discontinuation/ switch of this therapy and last follow-up visit up to 2 years. Cox regression will be used to obtain a predictor model of discontinuation. P value will be considered significant at <0.05. The SPSS v25 will be used to analyse the data collected from this study.

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