

1. TITLE

PROSAS STUDY – Persistence, Effectiveness and Real-World Outcomes in SpondylArthritis patients treated with Secukinumab

2. INTRODUCTION

Psoriatic arthritis (PsA) and ankylosing spondylitis (AS) are chronic inflammatory arthritis-associated diseases which can lead to functional disability and impaired quality of life.^{Errol Marcador não definido.}

Secukinumab, a recombinant high-affinity fully human monoclonal antibody targeting interleukin-17A (IL-17A), a cytokine involved in the pathogenesis of immune-mediated diseases, has been approved for the treatment of PsA and AS in adults. In the pivotal clinical studies, secukinumab showed good retention rate with approximately 80% of patients still on secukinumab at 2 years in both indications.^{1,2}

Notwithstanding, despite the growing number of SpA patients already treated with secukinumab, real-world data about the characterization of patients treated with this drug, as well as about its persistence and effectiveness is still sparse, most notably in Portugal. Thus, this non-interventional (secondary data using the registry of rheumatic diseases in Portugal – Reuma.pt) cohort study aims to first describe baseline characteristics of SpA patients treated with secukinumab in the portuguese daily practice setting (PHASE 1: Baseline patient characteristics), and secondly to measure secukinumab persistence, effectiveness and impact on relevant Patient Reported Outcomes (PROs), namely patients' function and quality of life (PHASE 2: persistence and effectiveness).

PHASE 1 will provide descriptive results about the characterization of patients who were treated with secukinumab in Portugal during 2017 and 2018 (and 2019, if possible and aiming to maximize available sample size), while PHASE 2 will provide relevant longitudinal data in the subset of patients who had time to be followed up in the registry.

3. RESEARCH TEAM

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1 Marzo-Ortega H, et al. Secukinumab provides sustained improvements in the signs and symptoms of active ankylosing spondylitis with high retention rate: 3-year results from the phase III trial, MEASURE 2. RMD Open. 2017 Dec 28;3(2):

2 McInnes IB, et al. Secukinumab sustains improvement in signs and symptoms of psoriatic arthritis: 2 year results from the phase 3 FUTURE 2 study. Rheumatology (Oxford). 2017 Nov 1;56(11):1993-2003.