SYNOPSIS

Title of Study: Efficacy and safety of anakinra (antagonist of the interleukin-1 receptor) in the treatment of periarticular inflammation in patients refractory to NSAID and / or steroids
EudraCT: 2013-005402-65 **Sponsor protocol code:** IIBSP-ANA-2013-163
Principal investigator: Arturo Rodríguez de la Serna
Study centres: Sant Pau Hospital, Elche Hospital
Studied period (years): October 2015 - April 2016
Phase of development: II
Objectives: To evaluate the efficacy of anakinra in the treatment of periarticular inflammation in patients with supraspinatus tendinitis refractory to NSAID and / or steroids.
Number of patients (planned): 20
Diagnosis and main criteria for inclusion: - Male and female patients over 18 years of age at the time of the screening visit. - Supraspinatus tendinitis, plantar fasciitis, trochanteric bursitis and / or lateral epicondylitis patients refractory to NSAIDs and / or corticosteroids, lack or loss of efficacy or contraindications. - Patients with a score on the VAS pain score greater than or equal to 6 cm - Patients able to understand the implications of the study and demonstrate it through voluntary signing of informed consent.
Test product product, dose, mode of administration and duration of treatment: Anakinra 100 mg/ml periarticular /once a week, minimum 1 dose and maximum 4 doses.
Reference therapy, dose and mode of administration: Not applicable
Criteria for evaluation: Efficacy - Evaluation of the patient's pain by VAS (0-10) Safety - Adverse events Time points: Basal, + 7 , +15, +30 and +60 days
Summary – Conclusions: A total of 10 patients were included, 6 in the Sant Pau hospital and 4 in the Elche Hospital. Of the 10 patients, 2 had a transient initial response and 8 had no response. For this reason, it was decided to suspend the study early. There were no serious adverse events.
Date of report: December 2016