

4.0 Abstract

Title: Observational Study; Clinical Effectiveness and Impact on Health-related Quality of Life in Peruvian Patients with Psoriasis after 16 weeks of adalimumab therapy
Rationale and Background: Since adalimumab authorization for active psoriasis in Peru, the local experience is very low.
Research Question and Objectives: The aim of this study is to obtain Peruvian data of clinical effectiveness; and impact in the health related quality of life with the use of adalimumab in psoriatic patients complying with the dosing and monitoring recommendations of the local approved label. For this, two main objectives are proposed: <ul style="list-style-type: none">- To assess the effectiveness at 16 weeks of therapy with adalimumab describing the proportion reaching a 75% reduction in the Psoriasis Area and Severity Index (PASI75).- To assess the impact on the health-related Quality of Life describing the proportion of patients reaching a minimal important difference in the Dermatology Life Quality Index (DLQI) score between 2.3 and 5 after 16 weeks of treatment with adalimumab.
Study Design: Post Marketing Observational Study
Population: Psoriatic participants will be enrolled in the study; who will receive adalimumab therapy at Peruvian hospitals/clinics.
Variables: Psoriasis Area and Severity Index (PASI75) assessed by physical examination, Dermatology Life Quality Index (DLQI) by standardized instrument using a CRF, Euro QOL 5D (EQ-5D) by preference-based instrument using a CRF, as well as adherence, compliance and adverse events were evaluated during the study.

Data Sources:

AbbVie supplied case report forms. These forms were used to transmit information collected during the study to the Principal Investigator, Abbott and regulatory authorities, as applicable. Case report forms were completed for each subject enrolled in this study. The investigator of the site reviewed the CRF for completeness and accuracy and signed and dated each set when indicated. All patient data entered in the patient's CRF were entry in the data management that were available for evaluation to Principal Investigator or his designee.

Study Size:

A total of 30 subjects were enrolled in this PMOS despite of the 75 originally planned in the protocol.

Data Analysis:

Proportions for categorical variables and means for numerical variables were used in the description of the study population. Similarly, proportions and 95% confidence intervals (CI) were used to show the distribution of the primary outcomes (PASI75, DLQI Score) as well as secondary outcomes (EQ-5D index).

Results:

A total of 30 participants were included in this study, of them 27 (90.0%) were men and the age mean was 51 (SD: 11), 46.7% of participants had PPD \leq 5 mm, but no one has findings compatible with tuberculosis. Of the 26 participants available for the primary analysis, 21 (78%; 95% CI: 61% – 95%) achieved PASI75. In addition, 92% (95% CI: 81% – 100%) achieved at least 2.3 decay in DLQI score at 16 weeks compared to baseline. Finally, the mean response of EQ-5D index increased from 0.48 (SD: 0.40) at baseline to 0.80 (SD: 0.32) at the end of 16 weeks of follow-up ($p = 0.003$). Only one participant had an adverse event (cellulitis) not related to the drug.

Discussion:

More than three quarters of participants achieved Psoriasis Area and Severity Index (PASI75) at Week 16 of follow-up. Besides, 92% of participants achieved 2.3 decay in the Dermatology Life Quality Index (DLQI) score at Week 16. Furthermore, adalimumab showed a mean decay in the PASI score, a mean decay in the DLQI score and a mean increment in the EQ-5D score over time with significant differences observed as early as Week 4 in comparison with baseline. There was only one not related adverse event reported in the study.