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### LONG-TERM EFFECTIVENESS AND SAFETY OF TRALOKINUMAB IN PATIENTS WITH SEVERE ATOPIC DERMATITIS

Lorenzo Cantarelli\*<sup>1</sup>, Marta Suárez González<sup>2</sup>, Marta García Bustinduy<sup>1</sup>, Sheila Otazo Pérez<sup>1</sup>, Marco Antonio Navarro Dávila<sup>1</sup>, Gloria Julia Nazco Casariego<sup>1</sup>

<sup>1</sup>Hospital Universitario de Canarias, La Laguna, Spain

<sup>2</sup>Hospital Universitario Nuestra Señora de Candelaria, Santa Cruz de tenerife, Spain

#### Introduction

The introduction into clinical practice of biological treatments with a highly specific focus on the IL-13 immune axis has revolutionized the landscape of Atopic Dermatitis (AD). Therefore, the objective of this study was to evaluate the medium- to long-term efficacy and safety of Tralokinumab in patients with AD at a tertiary hospital.

#### Materials and Methods

Retrospective observational study including all patients with AD treated with Tralokinumab from January 2022 to January 2026. The following demographic and clinical variables were evaluated based on data collected through the Farmatools electronic program: age, sex, duration of treatment, concomitant pathologies and previous use of biological treatment.

Treatment effectiveness was evaluated based on changes in the Eczema Area and Disease Severity Index (EASI), the Peak Pruritus Numerical Rating Scale (PP-NRS), and the Investigator Global Assessment (IGA) at weeks 0, 16 and 52. Effectiveness was defined as achieving at least EASI75, a reduction in PP-NRS of >3 points and an IGA of 0-1. The results were compared with baseline values.

The safety profile was determined by collecting adverse effects and classifying the degree of toxicity according to the Common Terminology Criteria for Adverse Events v. 5.0 scale.

#### Results

During the study period, a total of 24 patients were included (54.2% men (n=13); mean age: 39.5 years). Treatment with Tralokinumab lasted a mean of 16.8 months. Fifty percent of patients (n=12) had a concomitant condition: 29.2% rhinitis (n=7), 25% asthma (n=6), and 4.1% urticaria (n=1). Fifty-four point two percent of patients were biologic-naïve (n=13).

At week 0, the mean EASI score was 24.9 and the PP-NRS score was 7.6 points. 81.2% (n=13) had an IGA score of 3-4 at baseline.

28.5% of patients (n=4) achieved an EASI75 and 21.4% (n=3) achieved an EASI 90 at week 16. At week 52, 77.8% of patients (n=7) achieved an EASI 75 and 66.7% (n=6) achieved an EASI 90.

61.5% of patients (n=8) achieved a significant decrease in PP-NRS at week 16 and 66.7% (n=6) at week 52. Likewise, 54.5% (n=6) and 83.3% (n=5) achieved an IGA of 0-1 at week 16 and 52, respectively.

16.5% (n=4) experienced ocular toxicity during treatment, of which 25% (n=1) was grade III/IV. 4.1% of patients (n=1) had to discontinue treatment due to severe toxicity.

#### Conclusions

This study demonstrates that Tralokinumab is an effective and safe medium- to long-term alternative for the treatment of moderate to severe AD. More comprehensive studies with larger sample sizes will be needed in the future to confirm the results obtained.

