

# Tralokinumab real world clinical use: An observational cohort study of atopic dermatitis patients prescribed tralokinumab (TRACE)

**First published:** 07/02/2022

**Last updated:** 11/12/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS44659

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### Study ID

45677

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### DARWIN EU® study

No

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### Study countries

Belgium

Canada

France

- Germany
  - Italy
  - Netherlands
  - Spain
  - Switzerland
  - United Arab Emirates
  - United Kingdom
  - United States
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### **Study description**

This longitudinal observational study aims to assess changes in clinical signs and symptoms of atopic dermatitis (AD) in patients treated with tralokinumab in a real-world setting over a 1-year period. The secondary objectives are to observe safety in patients treated with Tralokinumab, describe the patients' characteristics, explore baseline predictors of clinical response, and describe the real-world use of Tralokinumab. The study enrolls patients with AD who are eligible for treatment with tralokinumab according to the local label (new users). Patients are followed up for approximately 1 year. The study will be conducted in max. 15 countries in Europe, North America and the United Arab Emirates. The primary outcome is AD severity (clear or almost clear: yes/no) measured by physician-assessed AD severity measures (IGA, EASI or SCORAD). Various PROs are collected if considered normal clinical practice. Additional information about demographics, medical history, AD treatment, AD location and adverse events will be collected.

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### **Study status**

Finalised

## Research institutions and networks

# Institutions

**IQVIA**

United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

Teodora Festini TEFES@leo-pharma.com

**Study contact**

[TEFES@leo-pharma.com](mailto:TEFES@leo-pharma.com)

### Primary lead investigator

Teodora Festini

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 25/05/2021

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### Study start date

Planned: 01/04/2022

Actual: 23/11/2021

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### **Data analysis start date**

Planned: 10/10/2024

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### **Date of final study report**

Planned: 24/01/2025

Actual: 09/07/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

LEO Pharma

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

To assess changes in clinical signs and symptoms of AD in patients treated with tralokinumab.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

ADTRALZA

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**Study drug International non-proprietary name (INN) or common name**

TRALOKINUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(D11AH07) tralokinumab

tralokinumab

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### **Medical condition to be studied**

Dermatitis atopic

## Population studied

### **Age groups**

- **Adult and elderly population ( $\geq 18$  years)**

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- Elderly ( $\geq 65$  years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

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### **Estimated number of subjects**

844

## Study design details

### **Outcomes**

- Change from baseline of patients achieving clear or almost clear skin after 12 months
- Mean change from baseline in peak pruritus NRS after 3, 6, 12 months
- AEs

- Baseline characteristics and predictors of clinical response
  - Association between prior use of systemic treatment and time to switching treatment
  - Co-mediation: TCSs, TCIs and non-topical treatments
  - Mean treatment dose, regimen and time to switch in tralokinumab - Mean change in DLQI after 3, 6, and 12 months
  - Change in WPAI-GH and Sleep NRS
  - AD-associated use of healthcare
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### **Data analysis plan**

This study is observational and epidemiological methods will be employed for data analyses. Descriptive analyses will be performed of all collected data. A subject disposition will be displayed showing all included subjects, reasons for withdrawal and completing the study. For the analysis of the primary and secondary objectives, the following methods will be used:

- Descriptive statistics
- Repeated measurement logistic regression models
- Repeated measurement ANCOVA model
- Cause-specific hazards and estimation of the Cumulative Incidence Function (CIF) Further details will be provided in a statistical analysis plan.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

## **Data sources (types)**

Electronic healthcare records (EHR)

Other

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## **Data sources (types), other**

Prospective patient-based data collection

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

# Data quality specifications

## **Check conformance**

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No