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

First published: 07/02/2022

Last updated: 23/04/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45677

EU PAS number

EUPAS44659

Study ID

45677

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Canada
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] Switzerland
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] United States

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.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Teodora Festini

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 25/05/2021

Study start date

Planned: 01/04/2022

Actual: 23/11/2021

Data analysis start date
Planned: 10/10/2024

Date of final study report
Planned: 24/01/2025

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

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

Name of medicine

ADTRALZA

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

TRALOKINUMAB

Medical condition to be studied

Dermatitis atopic

Additional medical condition(s)

Atopic Dermatitis

Population studied

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

822

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

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

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No