Atopic Dermatitis – Treatment Response EVALuation and UsEr Satisfaction with Tralokinumab in Standard Clinical Practice (ADValue)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000872

Study ID

1000000872

DARWIN EU® study

No

Study countries

Germany

Study status

Planned

Research institutions and networks

Institutions

Universitätsklinikum des Saarlandes Klinik f. Dermatologie, Venerologie und Allergologie

Contact details

Study institution contact

Claudia Pföhler info@uks.eu

Study contact

info@uks.eu

Primary lead investigator

Claudia Pföhler

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/07/2025

Study start date

Planned: 16/12/2025

Date of final study report

Planned: 31/03/2030

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

NIS-TRALO-2412

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Other

If ‘other’, further details on the scope of the study

Efficacy and safety study with no comparator

Data collection methods:

Primary data collection

Study Design

Non-interventional study design

Other

Non-interventional study design, other

A non-interventional, non-comparative, prospective, observational study with primary data collection in routine clinical practice.

Study drug and medical condition

Medicinal product name

ADTRALZA

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

TRALOKINUMAB

Anatomical Therapeutic Chemical (ATC) code

(D11AH07) tralokinumab

tralokinumab

Medical condition to be studied

Dermatitis atopic

Population studied

Short description of the study population

Adolescent (12 years and older) and adult patients with moderate-to-severe AD, eligible for treatment with tralokinumab (new users), during routine clinical care. The decision to start treatment in a patient with tralokinumab was taken before and independently of enrolment in the study.

Age groups

- Adolescents (12 to < 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

400

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)

Patient surveys

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

Unknown