A pan-European registry-based observational study of abrocitinib and conventional systemic therapies in moderate and severe atopic dermatitis (Dream to TREAT AD)

First published: 12/01/2024

Last updated: 10/03/2025

Study | Finalised

Administrative details

EU PAS number

EUPAS108468

Study ID

199009

DARWIN EU® study

No

Study countries

Denmark

Germany

Ireland

Netherlands

United Kingdom

Study description

This observational study will seek to characterise the profile of abrocitinib and conventional systemic treatment patients with moderate and severe atopic dermatitis in clinical practice in Europe through the involvement of 5 registries in Germany, Netherlands, UK, Ireland and Denmark. It will aim to describe the short- and long-term effectiveness of abrocitinib and conventional systemic therapies in a three-year follow-up period through the aggregated data analysis.

Study status

Finalised

Research institutions and networks

Institutions

St John's Institute of Dermatology

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 5; Amsterdam UMC, Amsterdam, Netherlands, Bispebjerg Hospital, Copenhagen, Denmark, University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany, Medical School Hannover, Hannover, Germany, Technical University Dresden, Dresden, Germany, University College Dublin, Dublin, Ireland, St John's Institute of Dermatology, St Thomas' Hospital, London, UK

Networks

European TREatment of ATopic eczema registry Taskforce (TREAT) (European TREAT Registry Taskforce)

- Denmark
- France
- Germany
- Italy
- Netherlands
- Portugal
- Spain
- Sweden
- United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Flohr Carsten

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2023

Actual: 10/05/2023

Study start date

Planned: 02/01/2023

Actual: 02/01/2023

Date of final study report

Planned: 01/06/2026

Actual: 09/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To describe abrocitinib and conventional systemic therapy patients' demographic details, AD diagnosis, comorbidities, prior and concomitant AD therapies and AD severity, initially separately for the study registers but then also in aggregated form.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational patient registries

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(D11AH08) abrocitinib

abrocitinib

(H02AB06) prednisolone

prednisolone

(L04AD01) ciclosporin

ciclosporin

(L04AX03) methotrexate

methotrexate

Medical condition to be studied

Dermatitis atopic

Population studied

Short description of the study population

200 abrocitinib patients and 200 patients on conventional systemics (methotrexate, ciclosporin, prednisolone)

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

400

Study design details

Outcomes

Baseline disease severity measured with physician- and patient-reported outcomes (o EASI, vIGA-AD (where available), POEM,PP-NRS, (C)DLQI ,demographic characteristics of the cohort, number of past systemic eczema treatments, age of eczema onset, pattern of prescription of systemic eczema treatment of interest at baseline, change in disease severity with physician- (EASI, vIGA-AD) and patient-reported outcomes (POEM, PP-NRS, CDLQI/DLQI) from baseline at week 4, 16 and subsequent visits (every 3-6 months) up to month 36 in patients treated with abrocitinib and conventional systemics stratified by line of AD treatment and concomitant AD therapy use.

Data analysis plan

Statistical assessments will be performed to describe study outcomes, using descriptive statistics, relative risks and/or odds ratos, 95% CI, P-values, or modelling where appropriate.

In the aggregated data analyses, incremental increases in the patient population size during the three year follow up period will be described in interim and final analyses.

For individual register dataset analyses, descriptive statistics will be provided separately, using a jointly developed standardized template.

For the aggregated data analyses, the following will be performed:

• Summary statistics will be presented for observed values of continuous endpoints at the baseline period, at each follow-up visit during the observation, and the changes from the baseline period.

• For further details on the data analyses, see the SAP.

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 source(s)

German Atopic Dermatitis Registry TREATgermany

The UK-Irish Atopic Eczema Systemic Therapy Register

TREAT NL/BE registry (TREatment of Atopic eczema, the Netherlands and Belgium)

Data source(s), other

TREAT NL/BE, A-STAR Ireland, A-STAR UK, SCRATCH Denmark

Data sources (types)

Disease registry

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name (other)

Study-specific harmonised dataset

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No