A 24-Month Prospective Observational Cohort Study Evaluating Oral Systemic Therapies in the Management of Adult Patients with Atopic Dermatitis in REAL-World Practice (AD-REAL)

First published: 29/10/2020

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS37841

Study ID

50366

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany

Spain

United Kingdom

Study description

Due to the limited data available on current clinical practice and new treatments entering the market, the study aims to describe treatment patterns of baricitinib and other oral systemic treatments. Therefore, the primary objective of this study is to report descriptively the proportion of patients with all-cause treatment discontinuation at Week 24 after initiation of a new oral systemic treatment at baseline for the baricitinib cohort and the all other oral systemic treatment cohort.

Study status

Ongoing

Research institutions and networks

Institutions

Syneos Health

United Kingdom

First published: 23/04/2015

Last updated: 06/03/2024

Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Catherine Reed

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/11/2020

Study start date

Planned: 07/05/2021

Actual: 15/12/2021

Date of final study report

Planned: 30/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

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:

Effectiveness study (incl. comparative)

Main study objective:

Post-launch prospective observational study to understand real-world treatment effectiveness over 24 months of AD patients who initiate or switch to a new oral systemic treatment

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

BARICITINIB

METHOTREXATE

MYCOPHENOLATE MOFETIL

AZATHIOPRINE

CICLOSPORIN

UPADACITINIB

ABROCITINIB

Medical condition to be studied

Dermatitis atopic

Population studied

Age groups

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

760

Study design details

Outcomes

To report descriptively the proportion of patients with all-cause treatment discontinuation at Week 24 after initiation of a new oral systemic treatment at baseline for (1) the baricitinib cohort and (2) the all other oral systemic treatment cohort, To characterize treatment patterns of oral systemic therapies used in clinical practice

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Data analysis plan

Kaplan-Meier analysis will be used to analyze the primary endpoint (ie, the proportion of patients discontinuing their initial treatment baricitinib, other oral systemic treatment) at Week 24 for assigned treatment cohorts at baseline.

Data management

Data sources

Data sources (types)

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