

The UK-Irish Atopic Eczema Systemic Therapy Register (A-STAR): Eli Lilly Engagement with A-STAR

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Study

Ongoing

Administrative details

EU PAS number

EUPAS108949

Study ID

199014

DARWIN EU® study

No

Study countries

☐ Ireland

☐ United Kingdom (Northern Ireland)

Study description

The A-STAR Study is linked to the European Treatment of Severe Atopic Eczema Taskforce (TREAT Europe). This EU PAS Entry is meant to reflect Eli Lilly's engagement with A-STAR to collect data for baricitinib to treat patients with atopic dermatitis. A-STAR is a multi-centre, prospective, observational clinical registry of patients with atopic eczema on systemic immuno-modulatory therapies. Children and adults with atopic eczema starting on, or switching to another, systemic immunomodulatory therapy are eligible via participating dermatology centres. The primary objective is to estimate the short- and long-term effectiveness of systemic immunomodulatory therapies. The study aims to monitor patients for at least 12 months and, if possible, for many years thereafter.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

meyers_kristin_joy@lilly.com

Primary lead investigator

Kristin Meyers

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/12/2020

Study start date

Actual: 16/03/2021

Date of final study report

Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly

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:

Disease epidemiology

Main study objective:

To collect long-term safety and effectiveness data on patients with atopic dermatitis treated with baricitinib in the UK.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

OLUMIANT

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

BARICITINIB

Medical condition to be studied

Dermatitis atopic

Population studied

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

100

Study design details

Data analysis plan

Please see ASTAR protocol for details: <https://astar-register.org/clinicians-and-participating-centres/>

Data management

Data sources

Data source(s), other

A-STAR United Kingdom (Northern Ireland)

Data sources (types)

[Disease registry](#)

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