A Retrospective study to analyse the treatment outcomes of patients with severe atopic dermatitis (AD) who were enrolled in the Early Access to Medicines Scheme (EAMS) for dupilumab

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Study Finalised

Administrative details

EU PAS number

EUPAS28596

Study ID

28597

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The aim of this study, funded by Sanofi is to retrospectively analyse treatment outcomes of patients with severe atopic dermatitis (AD) who were enrolled into the Early Access to Medicines Scheme (EAMS), a scheme by the Medicines and Healthcare products Regulatory Agency (MHRA). The medical rationale is to understand the efficacy of dupilumab for the treatment of AD in a real world clinical setting. Response to treatment will be assessed by the change from baseline in validated measures of AD disease severity including Eczema Area Severity Index (EASI). Investigator Global Assessment (IGA) and Dermatology Life Quality Index (DLQI). Sanofi did not proactively collect efficacy data for patients treated with dupilumab during EAMS but following faesability analysis, it is evident that clinicians collect severity scores as part of routine clinical practice. Patient consent was obtained at the start of EAMS. Data will only be collected for patients who consented to data collection.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

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Institution

NA

University Hospital Southampton NHS Foundation Trust Southampton, UK, Belfast Health & Social Care Trust Belfast, UK, University Hospitals Birmingham NHS Trust Birmingham, UK, University Hospitals Bristol NHS Foundation Trust Bristol, UK, Royal Devon and Exeter NHS Foundation Trust Exeter, UK, Leeds Teaching Hospitals NHS Foundation Trust Leeds, UK, Sheffield Teaching Hospitals NHS Foundation Trust Sheffield, UK, Portsmouth Hosptials NHS Foundation Trust Portsmouth, UK

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rout Raj

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/03/2018

Study start date

Actual: 22/03/2018

Date of final study report

Actual: 29/08/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

QSD-012814 Protocol HEOR template EAMS outcome analysis v2.0.pdf (275.53 KB)

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

DUPILL09236

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To retrospectively analyse the treatment outcomes of patients with severe Atopic Dermatitis (AD) who were enrolled in the Early Access to Medicines Scheme (EAMS) for dupilumab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

DUPILUMAB

Medical condition to be studied

Rebound atopic dermatitis

Population studied

Short description of the study population

Severe atopic dermatitis (AD) who have received treatment with dupilumab through the Early Access to Medicines Scheme (EAMS) for more than 3 months.

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)

Special population of interest

Other

Special population of interest, other

Severe atopic dermatitis (AD)

Estimated number of subjects

65

Study design details

Outcomes

To describe the change in EASI score compared to baseline (EAMS enrolment) in patients who have received ≥ 12 weeks of treatment with dupilumab, To describe the change in IGA score compared to baseline (EAMS enrolment) in patients who have received ≥ 12 weeks of treatment with dupilumab To qualitatively describe clinician opinion about patient response to dupilumab (from retrospective review of patient notes)

Data analysis plan

The analysis mainly comprised descriptive statistics. Continuous variables were summarized using mean and standard deviation, with minimum and maximum values reported to provide the range. Categorical variables were summarized as

frequency and proportion.Inferential statistics were used to assess the statistical significance of observed differences for the 16 +/-4 weeks' timeframe. For continuous scale variables a paired samples t-test was performed. For ordinal variables a Wilcoxon Signed Ranks test was performed. Pearson's correlations were performed to assess the relationships between different measures of severity. No imputation was performed for missing data. Missing values were excluded from relevant analyses. Precise sample sizes are reported for each analysis. The analysis was conducted using IBM SPSS Statistics software (version 24).

Documents

Study results

EAMS Outcomes Report FINAL_DUPILL09236 signed.pdf (1.08 MB)

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)

Other

Data sources (types), other

Data collected in an anonymised format by members of the direct care team from patient medical records.

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