A Retrospective Evaluation of Conjunctivitis and Keratitis Among Individuals with Moderate-to-severe Atopic Dermatitis Treated with Dupilumab in the United States (US)

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Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42462

EU PAS number

EUPAS42461

Study ID

42462

DARWIN EU® study

No

Study countries

United States

Study description

The objective of this study is to investigate the rate of occurrence, risk factors, and characteristics of conjunctivitis and keratitis-related events and their management among individuals with moderate-to-severe atopic dermatitis (AD) and within the context of dupilumab use in a real-world setting. To best achieve this goal, the first step will be to develop validated claims-based algorithms for moderate-to-severe AD and conjunctivitis and keratitis-related events (henceforth referred to as conjunctivitis and keratitis in this protocol). Primary Objectives: • Objective 1: To develop and validate claims-based algorithms to identify moderate-to-severe AD, conjunctivitis, and keratitis by using medical record review and standardized criteria among individuals seen for clinical care in the US. • Objective 2: To identify demographic, treatment-related, and clinical characteristics associated with conjunctivitis and keratitis among individuals with moderate-to-severe AD in the US. • Objective 3: To quantify the risks of conjunctivitis and keratitis in dupilumab initiators and dupilumab naïve individuals with clinically similar moderate-to-severe AD in the US. Secondary Objective: • Objective 4: To describe patterns in treatment management for conjunctivitis and keratitis among individuals exposed to dupilumab and with moderate-to-severe AD in the US.

Study status

Finalised

Research institutions and networks

Institutions

Regeneron Pharmaceuticals

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Institution

Contact details

Study institution contact

Study Director Regeneron

Study contact

clinicaltrialdisclosureteam@regeneron.com

Primary lead investigator

Study Director Regeneron

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 23/08/2021

Study start date

Planned: 23/08/2021

Actual: 23/08/2021

Date of final study report

Planned: 15/09/2023

Actual: 13/10/2023

Sources of funding

- Non-for-profit organisation (e.g. charity)
- Pharmaceutical company and other private sector

More details on funding

Regeneron Pharmaceuticals, Inc., Sanofi

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

R668-CON-2052

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

An observational retrospective cohort study will be conducted within a US claims database. Algorithms to identify individuals with moderate-to-severe AD, conjunctivitis, and keratitis will be developed within the claims data and validated using medical record review. (See Brief Description for individual main objectives).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

DUPIXENT

Medical condition to be studied

Conjunctivitis

Dermatitis atopic

Keratitis

Population studied

Age groups

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

1400

Study design details

Outcomes

Conjunctivitis and keratitis cases will be identified among the following populations: • AD source population (Objective 1/algorithm validation) • Moderate-to-severe AD study population (Objective 2) • Dupilumab initiators and other AD therapy users among the moderate-to-severe AD patients (Objectives 3 and 4)

Data analysis plan

To assess the exposure and outcome algorithms, positive predictive value (PPV) and conditional sensitivity along with 95% confidence intervals will be calculated. The key variables for each propensity score matched study group will be summarized using descrip tive statistics. Incidence rates of the outcomes will be reported with 95% confidence intervals and adjusted rate ratios will be used for comparisons.

Documents

Study results

CON2052_EADV+Abstract_Final+Draft_05222023 clean_.pdf(146.94 KB)

Data management

Data sources

Data source(s), other

Optum Research Database United States

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

Medical Chart review

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