Incidence rates of Cutaneous T-Cell Lymphomas (CTCL) among patients with atopic dermatitis (AD)

First published: 11/01/2023

Last updated: 11/01/2023

Study Finalised

Administrative details

EU PAS number

EUPAS50516

Study ID

50517

DARWIN EU® study

No

Study countries

Germany

United Kingdom

Study description

This is a cohort study describing population incidence rates of cutaneous T-cell lymphomas (CTCL), patient-level incidence rates of CTCL following diagnosis of atopic dermatitis (AD), and patient-level incidence rates of CTCL following treatment for severe AD. The study population was the general population in the UK and patients visiting general practices in Germany.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/10/2022

Actual: 31/10/2022

Study start date
Planned: 31/10/2022

Actual: 31/10/2022

Date of final study report
Planned: 16/12/2022

Actual: 19/12/2022

Sources of funding

- EMA

Study protocol

Analysis-Plan-AD and CTCL-Nov 2022-for publication.pdf (1.12 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

This study aimed to estimate: i. incidence rates of cutaneous T-cell lymphomas (CTCL) in the general adult population ii. incidence rates of CTCL in adult patients with diagnosis of atopic dermatitis (AD) iii. incidence rates of CTCL in adult patients receiving treatment for severe AD

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Cutaneous T-cell lymphoma

Population studied

Short description of the study population

The study focused on general population in the UK and patients visiting general practices in Germany identified from the IMRD databases to determine the incidence rates of primary cutaneous T-cell lymphoma.

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

Patients with cutaneous T-cell lymphoma

Estimated number of subjects

1.000

Study design details

Outcomes

Cutaneous T-cell lymphomas, Event rates for CTCL in the general population were stratified by sex, age group and year. Event rates among patients with AD were stratified by sex and age

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Data analysis plan

This is a cohort study describing population incidence rates of cutaneous T-cell lymphomas (CTCL), patient-level incidence rates of CTCL following diagnosis of atopic dermatitis (AD), and patient-level incidence rates of CTCL following treatment for severe AD.

Documents

Study results

FINAL-REPORT-AD and CTCL-Dec2022-for publication.pdf (1.92 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 source(s)

IQVIA Disease Analyzer Germany

IQVIA Medical Research Data - OMOP

Data sources (types)

Electronic healthcare records (EHR)

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