Population incidence rates of pemphigoid in six European countries

First published: 22/05/2023

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS104284

Study ID

104285

DARWIN EU® study

No

Study countries

France

Germany

Italy

Romania

United Kingdom

Study description

A cohort study describing incidence rates of pemphigoid across six European databases, stratified by age, sex and year of diagnosis as well as by season of diagnosis (Autumn, Winter, Spring, Summer)

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

Robert Flynn

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 10/05/2022

Actual: 10/05/2022

Study start date
Planned: 10/05/2022

Actual: 10/05/2022

Date of final study report
Planned: 08/07/2022

Actual: 08/07/2022

Sources of funding

- EMA

Study protocol

Analysis Plan_Pemphigoid_20220510.pdf (995.61 KB)

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:

To describe the background incidence rate of pemphigoid stratified by age, sex, year of diagnosis and season of diagnosis

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Pemphigoid

Mucous membrane pemphigoid

Population studied

Short description of the study population

Pemphigoid patients identified from the European database which cover primary health care users from France, Germany, UK, Spain, Italy and Romania.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Term newborn infants (0 – 27 days)
- 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

Pemphigoid patients

Estimated number of subjects

1.856

Study design details

Outcomes

new onset of pemphigoid

Data analysis plan

Patients were required to have a minimum observation time of 365 days prior to entering into each period in order to establish whether events observed during the period are incident (first-ever) cases. The study period was from 2015 to 2019. The numerator consisted of the number of patients who experienced new onset of pemphigoid diagnosis during the yearly or quarterly time period. Patients with any recorded baseline history of pemphigoid were excluded and patients were only able to contribute one event each. For the denominator, as with the numerator, patients with a baseline history of pemphigoid at the start of each quarter or year were excluded. Patient follow-up time was truncated at the occurrence of the first event after which they did not contribute to the analysis. Incidence rate = (number of new onset events) / (total follow up time (years)), was calculated for the entire population and stratified by year, season, gender and age.

Documents

Study results

FINAL_Report_Pemphigoid_20220708.pdf (1.3 MB)

Data management

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

THIN® (The Health Improvement Network®)

Disease Analyzer - OMOP

Data sources (types)

Drug dispensing/prescription data

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