Background incidence rates of Interstitial Lung Disease

First published: 20/01/2023

Last updated: 13/03/2024



Administrative details

EU PAS number

EUPAS50623

Study ID

50624

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

Study description

This was a cohort study describing incidence rates of ILD in the general population. The study population was the general population (UK), patients visiting general practices (France), and patients visiting general or specialized practices (Germany).

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator Valentijn De Jong

Study timelines

Date when funding contract was signed Planned: 26/09/2022 Actual: 26/09/2022

Study start date Planned: 26/09/2022 Actual: 26/09/2022

Date of final study report Planned: 16/12/2022 Actual: 13/01/2023

Sources of funding

• EMA

Study protocol

FINAL-Analysis-Plan-Background rates ILD - for publication.pdf(1.02 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:

The objective of the study was to describe incidence rates of ILD in the general population and stratified by gender, age, and year

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Interstitial lung disease

Population studied

Short description of the study population

The study focused on general population and patients visiting general practices in Germany and France identified through IMRD databases to determine the incidence rates of interstitial lung disease.

Age groups

Preterm newborn infants (0 – 27 days) Term newborn infants (0 – 27 days) Infants and toddlers (28 days – 23 months) 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)

Special population of interest

Other

Special population of interest, other

Patients with interstitial lung disease

Estimated number of subjects

9500

Study design details

Outcomes

Interstitial lung disease

Data analysis plan

This was a cohort study describing incidence rates of ILD in the general population.

Documents

Study results

FINAL-Report-Background rates ILD - for publication.pdf(1.93 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) Disease Analyzer - OMOP 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