DARWIN EU® - Characterising interstitial lung disease in Europe

First published: 24/05/2024

Last updated: 05/02/2025





Administrative details

Study description

EU PAS number	
EUPAS100000172	
Study ID	
100000172	
DARWIN EU® study	
Yes	
Study countries	
France	
Germany	
Spain	
United Kingdom	

Rationale and background

Interstitial lung disease (ILD) is a heterogenous group of respiratory disorders affecting the interstitium of the lungs. Drug-induced ILD are adverse drug reactions from a wide range of drugs, many of which can be life-threatening diseases. Measuring the incidence of ILD and characterisating its population in Europe may guide signal detection validation discussions for drug-induced ILD.

Research questions

What were the incidence, the characteristics and overall survival of patients diagnosed with ILD and ILD-subtypes in four European countries in the period 2010-2022?

Objectives

The objectives are to measure (i) the incidences of ILD, stratified by age, sex and calendar time (obj. 1); (ii) to characterise the patients with ILD in terms of age, sex, comorbidities, risk factors and concomitant medications (obj. 2); and (iii) to measure the survival rates of patients diagnosed with ILD stratified by age, sex and calendar time (obj. 3) in four European countries. These objectives will be investigated for ILD overall and as well for the two most common ILD subtypes (alveolitis, pneumonitis and lung fibrosis).

Research methods

Study design

Cohort study with population-level descriptive epidemiology and patient-level characterisation

Population

All patients in the databases newly diagnosed with ILD in the period 1st January 2010 to 31st December 2022 with at least 365 days of data visibility prior to the date of first ILD diagnosis.

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Condition of interest

ILD and ILD-subtypes (pulmonary fibrosis, alveolitis, pneumonitis,)

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)
☐ Netherlands
First published: 03/11/2022
Last updated: 02/05/2024
Institution

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)
Belgium
Croatia
Denmark
Estonia

Finland
France
Germany
Greece
Hungary
Italy
☐ Netherlands
■ Norway
Portugal
Spain
Sweden
United Kingdom
First published: 01/02/2024
Last updated: 30/04/2025
Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Katia Verhamme

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/04/2024 Actual: 11/04/2024

Study start date

Planned: 23/05/2024 Actual: 23/05/2024

Date of final study report

Planned: 30/08/2024

Sources of funding

EMA

Study protocol

DARWIN EU_D2.2.3_Protocol_P3-C1-005_v2.1.pdf (1.18 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

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Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Cohort study with population-level descriptive epidemiology and patient-level characterisation

Main study objective:

The objectives are to measure (i) the incidences of ILD, stratified by age, sex and calendar time (obj. 1); (ii) to characterise the patients with ILD in terms of age, sex, comorbidities, risk factors and concomitant medications (obj. 2); and (iii) to measure the survival rates of patients diagnosed with ILD stratified by age, sex and calendar time (obj. 3) in four European countries. These objectives will be investigated for ILD overall and as well for the two most common ILD subtypes (alveolitis,/pneumonitis and lung fibrosis).

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

All patients in the databases newly diagnosed with ILD in the period 1st January 2010 to 31st December 2022 with at least 365 days of data visibility prior to the date of first ILD diagnosis.

Age groups

ΑII

Study design details

Setting

This study will be conducted using routinely collected data from four databases in four European countries. All databases were previously mapped to the OMOP Common Data Model (CDM).

Documents

Study results

DARWIN EU_Report_P3-C1-005_ILD_characterisation_V3.pdf (3.99 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)

Clinical Practice Research Datalink (CPRD) GOLD

Disease Analyzer - OMOP

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Clinical Data Warehouse of the Bordeaux University Hospital

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Unknown Check completeness Unknown

Check stability

Check conformance

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No