DARWIN EU® - Characterising interstitial lung disease in Europe

First published: 24/05/2024

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000172

EU PAS number

EUPAS1000000172

Study ID

1000000172

DARWIN EU® study

Yes

Study countries

France

Germany

Spain

United Kingdom

Study description

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.

Variables

Condition of interest

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

Study status

Ongoing

Research institution 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 **Educational Institution** **ENCePP partner**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

Belgium

Croatia

Denmark

Estonia

Finland

France

Germany

Hungary

Netherlands

Norway

Portugal

Spain

United Kingdom

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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

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

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

All

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

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

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No