DARWIN EU® - Characterising interstitial lung disease in Europe

First published: 24/05/2024
Last updated: 11/07/2024

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.
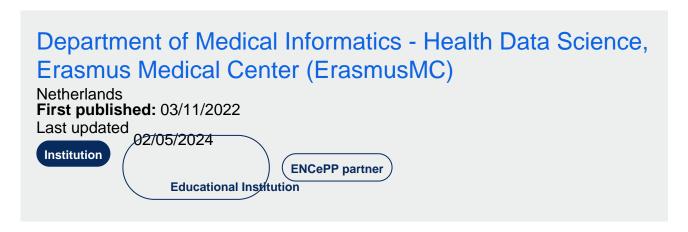
Variables
Condition of interest
ILD and ILD-subtypes (pulmonary fibrosis, alveolitis, pneumonitis,)

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
First published: 01/02/2024
Last updated   11/06/2024

Network

Contact details

Study institution contact
Ilse Schuemie

Study contact

study@darwin-eu.org
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 data collection

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).

Data management

Data sources

Data source(s)
Clinical Practice Research Datalink (CPRD) GOLD
Disease Analyzer - OMOP
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

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No