Incidence and Prevalence of Interstitial Lung Disease and their progressive fibrosing phenotypes in 6 European Countries (PERSEIDS)

First published: 29/05/2020

Last updated: 09/12/2020

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/38521

EU PAS number

EUPAS34861

Study ID

38521

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Denmark
- [ ] Finland
- [ ] Greece
- [ ] Norway
- [ ] Portugal

Study description

Non-interventional, epidemiological, retrospective, site-level (aggregated data) study in 6 European countries (Belgium, Denmark, Finland, Greece, Norway and Portugal). The study will be performed in two phases, both of them based on existing data. The main research questions are: in Phase 1 to know the epidemiology (incidence rate and prevalence) of ILD, SSc and some specific ILD-subtypes by collecting aggregated data from 18 hospital databases, in Phase 2, to describe the prevalence of progressive phenotypes and UIP pattern among other (non-IPF) fibrosing ILD subjects by looking into 100 patient files and reviewing lung function, hospitalizations, oxygen use, deaths and imaging results during a 2-year (retrospective) period.

Study status

Finalised

Research institutions and networks

Institutions

TFS HealthScience (TFS)

Sweden

First published: 01/02/2024

Last updated: 03/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Multiple centres: 14 centres are involved in the study

Contact details

Study institution contact

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Primary lead investigator

Stéphane Soulard

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/01/2019

Actual: 15/01/2019

Study start date
Planned: 15/05/2019

Actual: 15/05/2019

Data analysis start date
Actual: 20/04/2020

Date of final study report
Actual: 09/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim International GmbH (BI)

Study protocol

SSc_ILD_Epi_(BIN1029)_Protocol_Final_20190429 (002)_clean.pdf(1.85 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

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:

Phase 1: To estimate, in 6 European countries, the incidence rate and prevalence of SSc, ILD, ILD associated to SSc (SSc-ILD), Fibrosing ILD, IPF and other fibrosing ILD. Phase 2: To estimate, in 6 European countries, the percentage of other (non-IPF) fibrosing ILD patients with a progressive phenotype (PF-ILD), UIP pattern and PF-ILD with UIP pattern

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective epidemiological study

Study drug and medical condition

Medical condition to be studied

Interstitial lung disease

Idiopathic pulmonary fibrosis

Hypersensitivity pneumonitis

Sarcoidosis

Mixed connective tissue disease

Additional medical condition(s)

Idiopathic non-specific interstitial pneumonia, Unclassifiable idiopathic interstitial pneumonia, Exposure-related interstitial lung disease, Other fibrosing interstitial lung disease, Systemic sclerosis-associated interstitial lung disease Rheumatoid arthritis-associated interstitial lung disease and Other diffuse connective tissue disease.

Population studied

Short description of the study population

Phase 1: all adults listed in source databases during 2014-2018.

Phase 2: first 100 patients at each database with a code/keyword for any non-IPF F-ILD from 2016.

Inclusion criteria

- Phase 1: All adult subjects listed in the participating hospital databases aged ≥18 in each calendar year of the index period (i.e. 2014, 2015, 2016, 2017 and 2018) will constitute the source population, which will be used to identify the cases for each studied condition

 Phase 2: First 100 patients23 with a health encounter at sites participating in Phase 2 from 1st January 2016 onwards including an ICD/keyword for any "other (non-IPF) fibrosing ILD" (as defined in Phase 1)

Age groups

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)

Estimated number of subjects

12990656

Study design details

Outcomes

Phase 1: Crude prevalence and crude incidence rate of SSc, ILD, SSc-ILD, fibrosing ILD, IPF and other fibrosing ILD per 100 000 persons in each site/country, overall for the study period (2014-2018) and annuallyPhase 2: Percentage of other (non-IPF) fibrosing ILD patients with PF-ILD, UIP pattern and PF-ILD with UIP pattern, Phase 1: Crude prevalence and incidence rate for each clinical ILD and fibrosing ILD diagnosis overall for the study period (2014-2018) and annually. Phase 2: PPV, overall and by country and site, of the algorithm used for identifying fibrosing ILD (non-IPF) cases in Phase 1.

Data analysis plan

Statistical analyses will be of exploratory and descriptive nature. The study is not designed to confirm (or refute) pre-defined hypotheses.Descriptive analyses will be conducted to report the results of this study. Continuous variables will be presented as mean values, medians, ranges, interquartile range (IQR), and standard deviations and categorical variables will be presented as absolute and relative frequencies, together with 95% confidence intervals.

Documents

Study results

PERSEIDS_abstract_09December2020.pdf(549.47 KB)

Data management

Data sources

Data source(s)

Danish registries (access/analysis)

Auria Clinical Informatics (FinOMOP)

Data sources (types)

Other

Data sources (types), other

Hospital medical records and national/regional registers

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