Global Evaluation of the Interstitial Lung Disease Diagnostic Pathway (Global ILD-MDT study)

First published: 13/12/2017

Last updated: 08/08/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/22003

EU PAS number

EUPAS22002

Study ID

22003

DARWIN EU® study

No

Study countries

☐ Italy

United Kingdom

Study description

This two-phase study aims to characterise the global practice of diagnosing interstitial lung disease (ILD) and identify the features of ILD multidisciplinary team (MDT) meetings associated with more accurate diagnosis of ILD. Phase I is a global, standardised, systematic evaluation of the diagnostic process employed by a range of dedicated and non-dedicated ILD centres worldwide. An electronic questionnaire will be distributed through local leads, and national and international consortia. A pragmatic “strategic-opportunistic” approach will be taken, combining easily-scalable electronic data capture with local expertise to invite responses from a wide and representative range of (ultimately self-selecting) clinics and centres.Phase II is a global MDT ILD case review and diagnosis study to assess the diagnostic agreement across ILD MDTs and assess the diagnostic accuracy of ILD MDTs. Appropriate definition of these Phase II design components will be critical to the robustness and relevance of the study. The Phase II definition of an MDT, and the study’s geographical scope and case mix distribution, will aim to reflect real-life (as far as is practically possible) as established in Phase I. Centres identified in phase I will be invited to participate. Participants will be sent digitised reference cases, including pathology data, and diagnostic responses will be collected. Diagnostic accuracy will be determined against the diagnosis given by the reference case provider, against an expert MDT with global representation, and where possible, against the diagnostic inference of available follow up data.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 500 centres are involved in the study

Networks

Respiratory Effectiveness Group (REG)

- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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Network **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Luca Richeldi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/08/2016

Actual: 01/08/2016

Study start date

Planned: 10/11/2016

Actual: 10/11/2016

Data analysis start date

Planned: 01/02/2017

Actual: 01/02/2017

Date of interim report, if expected

Planned: 01/12/2017

Actual: 01/03/2017

Date of final study report

Planned: 27/11/2017

Actual: 27/11/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Financial: Roche, Boehringer Ingelheim and Three Lakes Partnership, in kind: Veracyte

Study protocol

GlobalILDEvaluation_Protocol060616.pdf(889.77 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

REG-RES1505

Methodological aspects

Study type

Study topic:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Diagnostic practice/accuracy

Data collection methods:

Primary data collection

Main study objective:

To identify features of ILD MDTs associated with more accurate diagnosis of IPF with a view to improving diagnostic accuracy and patient stratification to optimise treatment outcomes worldwide.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Interstitial lung disease

Population studied

Short description of the study population

Interstitial lung disease patients.

Age groups

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

Interstitial Lung Disease (ILD) patients

Estimated number of subjects

60

Study design details

Data analysis plan

Phase I analysis will be descriptive, comparing reported diagnostic practices by region, country economic status, and participant expertise. Phase II analysis will also be descriptive, with the use of agreement measures such as Cohen's Kappa statistic to explore diagnostic agreement. Diagnostic accuracy compared to the several different reference groups: the diagnosis of the clinican providing the case details, the diagnosis of an expert MDT with global representation, the diagnosis as indicated by available follow-up data.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Data for both phases will be generated through completion of an electronic questionnaire by participating centres.

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

Unknown