A prospective, observational study on the correlations between change in lung function and change in cough and dyspnoea in patients with connective tissue disease-associated progressive fibrosing INTErstitial luNg diseaSE (CTD associated PF-ILD) treated with nintedanib (INTENSE)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49654

EU PAS number

EUPAS49653

Study ID

49654

DARWIN EU® study

No

Study countries

☐ Greece

Study description

A non-interventional, multicentre study based on newly collected data on patients with CTD-associated PF-ILDs who are eligible for treatment with nintedanib in Greece as per routine clinical practice. The primary objective of this study is to investigate the correlation between changes from baseline at Month 24 in FVC % pred. and changes from baseline at Month 24 in dyspnoea score points and cough score points as measured with the L-PF questionnaire over 24 months of nintedanib treatment in patients with CTD suffering from chronic fibrosing ILD with a progressive phenotype (excluding IPF)

Study status

Planned

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

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Primary lead investigator

Dimitra Psomali

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/05/2022

Study start date

Planned: 30/11/2022

Data analysis start date

Planned: 29/01/2027

Date of final study report

Planned: 31/05/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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 type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The main objective of the study is to investigate the correlation between changes from baseline at Month 24 in FVC % pred. and changes from baseline at Month 24 in dyspnoea score points and cough score points as measured with the L-PF questionnaire over 24 months of nintedanib treatment in patients with

CTD suffering from chronic fibrosing ILD with a progressive phenotype (excluding IPF).

Study drug and medical condition

Name of medicine

OFEV

Medical condition to be studied

Pulmonary fibrosis

Additional medical condition(s)

Connective tissue disease

Population studied

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

120

Study design details

Outcomes

• The correlation between changes from baseline at Month 24 in FVC % pred. and changes from baseline at Month 24 in dyspnoea symptom score points • The correlation between changes from baseline at Month 24 in FVC % pred. and changes from baseline at Month 24 in cough symptom score points, • The correlation between change from baseline at Month 24 in FVC mL and change from baseline at Month 24 in dyspnoea symptom score • The correlation between change from baseline at Month 24 in FVC mL and change from baseline at Month 24 in cough symptom score • The correlation between baseline FVC % pred and change in dyspnoea symptom score from baseline at Month 24

Data analysis plan

Continuous characteristics will be presented in the form of mean values (SD) and/ or median values (IQR, expressed in the form 25th– 75th percentile), depending on the fulfilment of the normality assumption for their distribution. The normality assumption will be examined via graphical means (PP – plot, QQ – plot, and Histograms) alongside the statistical tests of Kolmogorov-Smirnov and Shapiro-Wilk, depending on the available valid sample size available for every variable examined. Categorical characteristics will be presented in the form of absolute (N) and relative frequencies (%). For the analysis of the primary outcome, the Pearson and/or the Spearman correlation coefficient (depending on the fulfilment of the normality assumption of their distribution) will be calculated, along with their 95% confidence intervals and the two-sided p-values. The respective null hypothesis will be rejected in case if $p \leq 0.025$ (Bonferroni correction for mult

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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