AN INTERNATIONAL STUDY TO CHARACTERIZE THE DISEASE BEHAVIOUR OF IDIOPATHIC PULMONARY FIBROSIS AND INTERSTITIAL LUNG DISEASE DURING THE PERI-DIAGNOSTIC PERIOD

Published: 01-02-2018
Last updated: 13-04-2024

The primary objective is to characterize the disease behavior of IPF and non-IPF ILD during the peri-diagnostic period.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational invasive

Summary

ID

NL-OMON47592

Source
ToetsingOnline

Brief title
MA39297

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
idiopathic pulmonary fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Roche Nederland B.V.
Source(s) of monetary or material Support: Roche

Intervention

Keyword: disease behaviour, idiopathic pulmonary fibrosis, interstitial lung disease, pulmonary function

Outcome measures

Primary outcome

Decline in Forced Vital Capacity (FVC) of patients with IPF during the

peri-diagnostic period

Secondary outcome

Please refer to paragraph 6.4.2. in the protocol

Study description

Background summary

Please refer to paragraph 1.3 in the protocol

Study objective

The primary objective is to characterize the disease behavior of IPF and non-IPF ILD during the peri-diagnostic period.

Study design

Please refer to paragraph 3.1 in the protocol

Study burden and risks

The (daily) spirometry can potentially cause shortness of breath, dizziness or coughing.
Other burdens are: wearing an accelerometer, a 6 minute walk test and optional bloodsample collections

Contacts

Public
Roche Nederland B.V.

Beneluxlaan 2a
Woerden 3446 GR
NL
Scientific
Roche Nederland B.V.

Beneluxlaan 2a
Woerden 3446 GR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Signed Informed Consent Form
2. Able to comply with the study protocol, in the investigator*s judgment * for example, the ability to use the provided spirometer and tablet and the ability to fill in the required patient reported outcomes questionnaires
3. Age *50 years
4. Suspicion of IPF/ILD: Radiological evidence of IPF/ILD in symptomatic patients (unexplained dyspnea on exertion and/or cough)

Exclusion criteria

1. Participation in any investigational study within 28 days prior to inclusion

2. History of clinically significant cardiac disease that could explain the patient*s symptomatology in the opinion of the investigator
3. Known history of any connective tissue disease, including, but not limited to, rheumatoid arthritis, scleroderma, systemic lupus erythematosus, or mixed connective tissue disease.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2018
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	01-02-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-03-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-08-2018
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-10-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-01-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	Eudract 2016-005114-22
CCMO	NL61874.056.17