Observational study in healthy subjects and patients with COPD to assess the relationship between clinical, imaging and biomarker measurements, and progression of emphysema over three years [FOOTPRINTS®]

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Study Finalised

Administrative details

EU PAS number

EUPAS1000001174

Study ID

1000001174

DARWIN EU® study

No

Study countries

Belgium
Canada
Denmark
Finland
Germany
Japan
Korea, Republic of
Poland
Spain
Sweden
United Kingdom
United States

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Boehringer Ingelheim

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/07/2016

Study start date

Actual: 22/07/2016

Date of final study report

Actual: 16/06/2021

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

Prot_352-2069_redacted.pdf (1.28 MB)

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Other study registration identification numbers and links

352.2069; NCT02719184

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:

Primary data collection

Study design:

Prospective, longitudinal study

Main study objective:

The overall objective of this study is to explore, if any of the biomarkers (soluble, functional imaging and physiological) assessed within healthy subjects, patients with COPD and patients with COPD and A1AT deficiency are correlated to COPD disease progression, particularly emphysema progression over 156 weeks.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Emphysema

Population studied

Short description of the study population

Healthy subjects, patients with COPD and patients with COPD and A1ATdeficiency

Study design details

Setting

Multi-center, multi-national study, ~ 12participating countries, ~ 50sites

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Outcomes

• Change of lung density assessed by CT over the course of the study

• Lung function decline over the course of the study

• Number, duration and severity of exacerbations during the course of the study

Documents

Study results

0352-2069_Synopsis.pdf (296.02 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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