Randomised Controlled Trial (RCT) vs Real Life initiative (RCT vs Real Life)

First published: 22/10/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7727

Study ID

28228

DARWIN EU® study

No

Study countries

United Kingdom

Study description

To determine the proportion of patients with COPD in the community who would meet inclusion/exclusion criteria of recently registered RCTs of long-acting bronchodilator therapy and to compare characteristics of COPD patients in

OPCRD with those from individual RCTs

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 20/08/2026

Institution **Educational Institution** **Laboratory/Research/Testing facility**

ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 17/07/2014

Study start date
Planned: 13/08/2014

Actual: 06/10/2014

Data analysis start date
Planned: 10/11/2014

Actual: 08/12/2014

Date of final study report
Planned: 15/12/2014

Actual: 11/03/2015

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 topic:

Disease /health condition

Study type:

Not applicable

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

Review /evaluation other studies

Main study objective:

To determine the proportion of patients with COPD in the Optimum Patients Care Research database (OPCRD) who would meet the inclusion and exclusion criteria to participate in recent RCTs of inhaled long-acting bronchodilator therapy.

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients with COPD in the Optimum Patients Care Research database (OPCRD) who would meet the inclusion and exclusion criteria to participate in recent RCTs of inhaled long-acting bronchodilator therapy

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Age groups

- 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

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

36.893

Study design details

Data analysis plan

Description of percentages of total OPCRD population of patients with COPD who would be eligbile for RCTs.Compare characteristics of eligible OPCRD population with reported characteristics of patients participating to RCT

Documents

Study publications

Halpin, D.M., Kerkhof, M., Soriano, J.B., Mikkelsen, H. and Price, D.B., 2016. ...

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.

Data sources

Data source(s), other

OPCRD United Kingdom

Data sources (types)

Electronic healthcare records (EHR)

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