Predictors of treatment choice in patients with COPD

First published: 06/07/2015

Last updated: 22/02/2024

Study Planned

Administrative details

EU PAS number

EUPAS10165

Study ID

10178

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A retrospective observational cohort study that investigates predictors of initial treatment choice in COPD patients.

Study status

Planned

Research institutions and networks

Institutions

Research in Real Life

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Institution

Contact details

Study institution contact

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Study contact

rebecca@rirl.org

Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/02/2014

Study start date
Planned: 17/02/2014

Date of final study report
Planned: 01/09/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceuticals

Study protocol

Encepp protocol_Prescription Patterns Manuscript.pdf (618.9 KB)

Predictors of treatment choice in patients with COPD_ENCePP protocol.pdf (618.4 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Main study objective:

To examine the changes in prescriptions patterns over time, in order to determine the potential driving factors behind GP prescribing for newly diagnosed COPD patients.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary 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

20.154

Study design details

Outcomes

Primary outcome will identify predictors of GP prescribing behaviour when treating newly diagnosed COPD patients with their first pharmacological therapy. It will assess the odds of being prescribed:• any initial COPD therapy vs. • no COPD therapy A further analysis will be conduted in regard to the odds of being prescribed: • maintenance therapy versus • short-acting agents/no therapy, To obtain the data required for exploring the primary outcomes, exploratories will be conducted to investigate the distribution of COPD pharmacological therapy in the main potential predictors (see appendix for full list). Results will be summarised and tested using chi-square to identify whether variation occurs among the categories.

Data analysis plan

Baseline characterisation of patients, summary statistics as a complete dataset and by treatment groups. Logistic regression analysis for all patients receiving first COPD therapy.Evaluate how the potential predictors outlined above could affect the choice of initial COPD therapy in terms of:a. Odds of being prescribed any initial COPD therapy vs. no therapyb. Odds of receiving initial COPD maintenance therapy vs. short-acting agents/no therapy

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 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

No