Predictors of treatment choice in patients with COPD

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/10178

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 institution and networks

Institutions

Research in Real Life

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Institution

Contact details

Study institution contact
David Price
Study contact

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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
20154

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

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