Profiling Inhalation Medication in COPD patients (PRIME)

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Study Ongoing

Administrative details

EU PAS number

EUPAS32862

Study ID

32863

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

(Inter) national guidelines advise that the prescription of pharmacological treatment should be individualized. Several tools have been created to assist and guide physicians in the selection of the most suitable inhalation treatment

for COPD patients. Nevertheless, it is unclear which patient characteristics guide pulmonologists in their decisions of the prescription of inhalation medication in COPD patients.Therefore, this study aims to describe the key patient characteristics that guided pulmonologists' prescription of inhalation medication in primary care COPD patients, using decision tree modelling.In 2007, an asthma/COPD(AC)-service was implemented in the North of the Netherlands to support general practitioners (GPs). In this system, pulmonologists support GPs in the diagnosis of their patients through an internet-based diagnostic dialogue. Patients complete questionnaires at home including the Clinical COPD Questionnaire (CCQ), the Asthma Control Questionnaire (ACQ) and medical history including allergies, medication use and smoking history. Spirometry and BMI measurement is performed by a technician of a laboratory. Pulmonologists see the data online through a protected website and send the GP a working diagnosis and treatment advice.We will include all COPD patients from the Asthma/COPD-service (AC-service) of whom medication advice has been given by the AC services pulmonologist between 2007 and 2017. The Chi-squared Automatic Interaction Detection (CHAID) method will be used to build the decision tree. The patient characteristics that will be used to develop the decision tree can be divided into three different categories: patients characteristics (e.g. age, gender, GOLD category), patient-reported outcomes (e.g. CCQ, ACQ), and spirometry outcome measures (e.g. FEV1, FVC, reversibility)

Study status

Ongoing

Research institutions and networks

Institutions

General Practitioners Research Institute (GPRI)

Netherlands

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Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

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Primary lead investigator

Janwillem Kocks

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/11/2018

Study start date

Actual: 03/12/2018

Date of final study report

Planned: 31/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim bv

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 type:

Non-interventional study

Scope of the study:

Other

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

Medication prescription

Main study objective:

This study aims to describe the key patient characteristics that guided pulmonologists’ prescription of inhalation medication in primary care COPD patients, using decision tree modelling.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective cross sectional

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

3544

Study design details

Outcomes

A decision tree which provides insight into the patient characteristics that guide pulmonologist in the prescription of inhalation medication to COPD patients and can be used to support GPs in daily clinical practice.

Data analysis plan

Two types of decision trees will be generated, the decision trees will be developed using the exhaustive Chi-squared Automatic Interaction Detection (CHAID) method. The first will contain predictors transformed into categorical variables using optimal binning or the binning method in CHAID, before binning the variables are checked for associations with the dependent variable. The second tree will contain predictors transformed in categorical variables using binning as well, but also contains predictors who are split at their clinically relevant cut-offs.

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