Evaluation of COPD Control and its Clinical Implications in a Real-Life UK Primary Care Population

First published: 16/08/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26337

EU PAS number

EUPAS10679

Study ID

26337

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This objective of this study, proposed by Dr. Marc Miravitlles at the Vall d’ Hebron University Hospital (Barcelona, Spain), is to validate the concept of Control in COPD, as outlined in Soler- Cataluna et al. 2014. The protocol has been developed, and the study will be overseen by an international steering committee comprising members of REG’s COPD Control Working Group. The protocol will make use of the OPCRD and the study will serve as an important hypothesis-generating pilot for an international prospective trial commencing later in the year.

Study status

Finalised

Research institutions and networks

Institutions

University Hospital Vall d’Hebron (HUVH)

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility**

Networks

Respiratory Effectiveness Group (REG)

- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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Network **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marc Miravitless

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/09/2015

Actual: 02/07/2015

Study start date
Planned: 01/09/2015

Actual: 01/08/2015

Date of final study report
Planned: 13/11/2015

Actual: 26/01/2016

Sources of funding

- Other

More details on funding

Respiratory Effectiveness Group (REG)

Study protocol

REG_COPD Control_UK Pilot Validation_300615_Protocol (1).pdf(1.29 MB)

Regulatory

Was the study required by a regulatory body?

Unknown

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:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

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

Testing the validity/effectiveness of the concept of COPD Control for potential patient management

Data collection methods:

Secondary use of data

Main study objective:

The purpose of this study is to validate the concept of Control in COPD, as outlined in Soler- Cataluna et al. 2014. First, COPD patients treated in UK

routine primary care will be characterised in terms or their control. Second, we will evaluate the clinical implications of control status in terms of COPD treatment management.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, historical database study

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

• Patients who have a COPD diagnosis:

o Physician-diagnosed COPD (presence of a COPD Read code); and/or

o Spirometry-defined COPD: post-bronchodilator FEV1/FVC<0.7

• Aged ≥40 years

• Current or ex-smokers

• Recorded COPD Questionnaire data

• ≥3 months’ continuous clinical records immediately prior to the index date
• ≥1 year of continuous clinical records immediately following the index date

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

300

Study design details

Outcomes

The primary endpoint of the study is the difference between patients controlled vs uncontrolled at baseline / index date in terms of:a) Time to first COPD exacerbationb) Exacerbation rate over the 1-year outcome period, Secondary endpoints1. Annual rate of COPD exacerbations in patients controlled vs non-controlled at index date.2. Time to the first exacerbation in patients controlled and non controlled at baseline3. Demographic and clinical characteristics associated with poor COPD control, specifically:(a) Age(b) Sex(c) Height(d) Weight(e) Therapy (f) Airway obstruction(g) Smoking history

Data analysis plan

Statistically significant results will be defined as $p<0.05$ and trends as $0.05 \leq p<0.10$. Association between COPD control status and the outcome period will be modeled using appropriate statistical methods. The statistical approach to be outlined in the statistical analysis plan (SAP) and will be approved by the lead investigator before the study commences.To evaluate the interaction of different patient (clinical and demographic) characteristics on the association between control status and outcomes, results will be stratified by:• Age• Sex• Height• Weight• Therapy (at index date)• Airway obstruction• Smoking history (pack years)

Documents

Study publications

Miravitlles M, Sliwinski P, Rhee CK, Costello RW, Carter V, Tan J, Lapperre TS,...

Data management

Data sources

Data source(s), other

Optimum Patient Care Research Database United Kingdom

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

The OPCRD comprises data extracted through the Optimum Patient Care (OPC) Clinical Service Evaluation and includes anonymised electronic medical records (EMRs) and patients' responses to disease-specific questionnaires. Data from these EMRs will be used.

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