Validation of the Concept of COPD Control in Clinical Practice

First published: 27/11/2015

Last updated: 04/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11656

Study ID

39103

DARWIN EU® study

No

Study countries

- Ireland
- Korea, Republic of
- Malta
- Poland
- Singapore
- Spain

United Kingdom

Study description

This is a 21-month pragmatic non-interventional trial comprising one baseline assessment and 4 follow-up visits. The primary aims of the study will be to evaluate the: 1). Levels of COPD control (vs poor COPD control) in an international cohort of routine care COPD patients, and 2). the clinical implications of control status.Secondary objectives of the study are to 1). Compare the utility of the COPD Control (as defined) as a tool to identify COPD impact and stability with the CAT and CCQ, 2). Evaluate the role of “adequate” (i.e. guideline-recommended) treatment prescribing on COPD control 3). Identify demographic and clinical characteristics associated with COPD control

Study status

Finalised

Research institutions and networks

Institutions

University Hospital Vall d’Hebron (HUVH)

Spain

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Last updated: 01/02/2024

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

Hospital de Alta Resolucion Granada, Spain, Royal College of Surgeons Dublin, Ireland, Hospital Universitari Vall d'Hebron Barcelona, Spain, Instituto de Investigacíon Sanitaria de Palma (IdISPa) Spain, Singapore General Hospital Singapore, Hospital of Laredo Spain, St. Mary's Hospital Seoul, Korea, Mater Dei Hospital Malta, Institute of Tuberculosis and Lung Disease Warsaw, Poland, Changi General Hospital (CGH) Singapore

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

Marc Miravitlles enquiries@REGresearchnetwork.org

Study contact

enquiries@REGresearchnetwork.org

Primary lead investigator

Marc Miravitlles

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/12/2015

Actual: 01/07/2015

Study start date

Planned: 11/08/2015

Actual: 27/08/2015

Date of final study report
Planned: 03/04/2018

Actual: 19/11/2019

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Novartis, Respiratory Effectivness Group

Study protocol

PROTOCOL_Validation of COPD Control_Clinical Study_REG-RES1503_update_161115.pdf (1.14 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:

Disease epidemiology

Other

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

Non-interventional study

Data collection methods:

Primary data collection

Main study objective:

The primary aims of the study will be to evaluate the:1). Levels of COPD control (vs poor COPD control) in an international cohort of routine care COPD patients, and2). The clinical implications of control status

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective pragmatic trial

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients older than 40 years with a diagnosis of COPD.

Inclusion criteria

Eligible patients must meet the following inclusion criteria, be/have:

1) Spirometry-defined COPD (i.e. post-bronchodilator FEV1/FVC<0.7)

2) Age ≥40 years

3) Smokers or ex-smokers of at least 10 pack-years

4) In stable state (as judged by the investigator) at point of recruitment

Exclusion criteria

Patients will be excluded from the trial if any of the following are true, they:

1) Have any chronic concomitant respiratory condition other than asthma or bronchiectasis (e.g. cystic fibrosis, lung fibrosis)

2) Have severe comorbidity with a life expectancy shorter than 2 years

3) Are unable to understand the instructions of the study or to fill the questionnaires

4) Are unwilling to sign the informed consent

5) Are participating in another clinical study or clinical trial.

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)

Special population of interest

Other

Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

328

Study design details

Outcomes

The composite endpoint is defined as occurrence of any of the following:1). For COPD: unscheduled visits to the physician, emergency room attendance2). An exacerbation of COPD3). All-cause: hospitalization or mortality, 1).Annual rate of exacerbations in patients controlled and uncontrolled at baseline2).Time to the first composite event, and time to first exacerbations in patients controlled and uncontrolled at baseline3).Comparison of CAT and CCQ tools to identify impact and stability in COPD4).Distribution of control level in those receiving guideline vs non-guideline recommended therapy5).Demographics

Data analysis plan

Intention-to-treat and per-protocol analyses will be undertaken. For the Intention-to-treat analysis, all patients entered into the study will be included in the analysis. For the per-protocol analysis, all patients entered who complete the study as per protocol (defined as attending baseline and all follow-up visits irrespective) will be included. For variables measured on the interval or ratio scale, these will include: Sample size (n) Percentage non-missing Mean

 Variance / Standard Deviation Range (Minimum / Maximum) Median Inter-quartile Range (25th and 75th percentiles)

Documents

Study publications

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

Miravitlles, M., Sliwinski, P., Rhee, C. K., Costello, R. W., Carter, V., Tan, ...

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

Kim, K. Y., Miravitlles, M., Sliwinski, P., Costello, R., Carter, V., Tan, J., ...

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)

Other

Data sources (types), other

Prospective patient-based data collection

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