Validation of the Concept of COPD Control in Clinical Practice

First published: 27/11/2015
Last updated: 04/06/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/39103

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 institution and networks

Institutions

University Hospital Vall d’Hebron (HUVH)
Spain
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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

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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

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