Evaluation of the undertreatment and disease outcomes for patients with coexisting Heart Failure and Chronic Obstructive Pulmonary Disease

First published: 30/03/2016

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/27216

EU PAS number

EUPAS12987

Study ID

27216

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

The objectives of this study are to assess the prevalence of comorbid diagnosed COPD and HF and to describe therapies prescribed and diagnostic tests undertaken by clinicians in real-life clinical practice for patients with COPD and/or HF. Additionally, it will evaluate the long-term respiratory and cardiovascular outcomes associated with the prescribed therapies for patients with comorbid COPD and HF. This study will be conducted using historical data from patients with COPD and/or heart failure. The prevalence of comorbid diagnosed COPD and HF will be assessed at the time of most recent data available for each patient, from all patients with a diagnosis of either COPD and/or HF. COPD and HF therapies prescribed and diagnostic tests undertaken will be considered in the year prior to most recent data available, between January 2010 to date for patients, comparing patients with comorbid COPD and HF to those with COPD alone and to those with HF alone. Cardiovascular and respiratory outcomes will be assessed for patients with comorbid COPD and HF, comparing those with adequate versus inadequate treatment for COPD/HF (according to guidelines). These outcomes will be assessed over at least one year and up to three years.

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/11/2015

Study start date
Actual: 05/02/2016

Date of final study report
Planned: 13/03/2017

Actual: 08/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To assess the prevalence of comorbid diagnosed COPD and HFTo describe therapies prescribed and diagnostic tests undertaken by clinicians in real-life clinical practice for patients with COPD and/or HF To evaluate the long-term respiratory and cardiovascular outcomes associated with the prescribed therapies for patients with comorbid COPD and HF

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Cardiac failure

Population studied

Short description of the study population

Patients with chronic obstructive pulmonary disease (COPD) and/or heart failure

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) and cardiac failure patients

Estimated number of subjects

129164

Study design details

Data analysis plan

The proportion of patients with a coexisting diagnosis of COPD and HF of all patients with a diagnosis of COPD and separately of all patients with a diagnosis of HF will be calculated.Diagnostic tests and prescription patterns will be reported as count and percentage and compared using conditional logistic regression within each severity group.Prescribing patterns will be presented graphically as a percentage of patients prescribed each treatment over the one year period for HF and COPD treatments separately.Rates of MACE, COPD exacerbations, HF hospitalizations and cardiovascular events after 1 year of

follow-up will be compared using conditional Poisson regression. Deaths after 1 year of follow-up will be compared using conditional logistic regression.Cox regression models will be used to analyze time to first MACE, COPD exacerbation, HF hospitalization, cardiovascular event and death.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Optimum Patient Care Research Database

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