Evaluation of patients with chronic obstructive pulmonary disease (COPD) and chronic kidney disease (CKD) who would benefit from aclidinium bromide treatment

First published: 17/10/2013

Last updated: 25/03/2015

Study Finalised

Administrative details

EU PAS number

EUPAS4902

Study ID

9109

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A retrospective, observational study characterising patient groups already within the OPCRD with chronic obstructive pulmonary disease (COPD) and chronic kidney disease (CKD) who may benefit from initiation of long acting muscarinic antagonist (LAMA) therapy or a switch from tiotropium for safety reasons

Study status

Finalised

Research institutions and networks

Institutions

Research in Real Life

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Emily Davis

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/09/2013

Actual: 17/09/2013

Study start date
Planned: 01/10/2013

Actual: 01/10/2013

Data analysis start date
Planned: 30/10/2013

Actual: 28/10/2013

Date of final study report
Planned: 31/12/2013

Actual: 30/12/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Almirall

Study protocol

R02713_Protocol_Almirall_ aclidinium_CKD_study_15_10_13.pdf (626.51 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

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 characterise populations of patients with chronic obstructive pulmonary disease (COPD) and chronic kidney disease (CKD) who could benefit from treatment with aclidinium bromide as an alternative to Tiotropium

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective observational database study

Study drug and medical condition

Medicinal product name

EKLIRA

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients aged ≥ 40 years who were diagnosed with chronic obstructive pulmonary disease (COPD) or chronic kidney disease (CKD)

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

Renal impaired

Other

Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

1.670

Study design details

Outcomes

To characterise the aclidinium bromide eligible population. The proportion of patients who are being incorrectly treated with tiotropium and the proportion of patients not receiving any LAMA therapy but that would be justified in having treatment, and could therefore be started on aclidinium bromide, will be evaluated.

Data analysis plan

Summary statistics will be calculated for the following variables by LAMA therapy and compared:• Demographics (including age, sex, BMI, smoking status)• Co-morbidities• Number of exacerbations in the year before the index date (ATS and clinical definition)• GOLD group status• CKD diagnostic codeFor

variables measured on the interval or ratio scale, summary statistics produced will be:• Sample size (n)• Percentage non missing• Mean• Variance/standard deviation• Range (minimum- maximum)• Median• Inter-quantile range (25th and 75th percentile)For categorical variable the summary statistics will include:• Sample size (n)• Range (if applicable)• Count and percentage by category (distribution)Outcomes will be compared using a Mann Whitney U test/Chi squared Test (for variables measured on the interval or ratio scale/ categorical variables respectively.)

Documents

Study publications

Price D, Davis E, Gilchrist A, West D, Kerklof M, Ryan D. Prevalence of chronic…

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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Retrospective observational database study using the Optimum Patient Care Research Database (OPCRD)

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