

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

**First published:** 17/10/2013

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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

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### Research in Real Life

**First published:** 01/02/2024

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**Institution**

### Contact details

#### Study institution contact

David Price [david@rirl.org](mailto:david@rirl.org)

**Study contact**

[david@rirl.org](mailto:david@rirl.org)

#### Primary lead investigator

Emily Davis

## Study timelines

### **Date when funding contract was signed**

Planned: 17/09/2013

Actual: 17/09/2013

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### **Study start date**

Planned: 01/10/2013

Actual: 01/10/2013

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### **Data analysis start date**

Planned: 30/10/2013

Actual: 28/10/2013

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### **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

## 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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**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 acclidinium bromide as an alternative to Tiotropium

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Retrospective observational database study

## Study drug and medical condition

### **Medicinal product name**

EKLIRA

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### **Medical condition to be studied**

Chronic obstructive pulmonary disease

## Population studied

### **Short description of the study population**

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

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### **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)
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### **Special population of interest**

Renal impaired

Other

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### **Special population of interest, other**

Chronic obstructive pulmonary disease (COPD) patients

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### **Estimated number of subjects**

1670

## **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.

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### **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 code

For

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...](#)

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## 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 \(EHR\)](#)

**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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

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## Data characterisation

**Data characterisation conducted**

No