

# Real-life effectiveness evaluation of the long-acting muscarinic antagonist aclidinium bromide (Eklira®) for the management of COPD in a routine UK primary care population - Study 1 (Real-life acceptability of Eklira)

**First published:** 19/05/2014

**Last updated:** 17/03/2015

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6573

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### Study ID

8872

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### DARWIN EU® study

No

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### Study countries

☐ United Kingdom

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### Study description

To evaluate the real-life effectiveness of the antimuscarine bronchodilator aclidinium bromide (Eklira®) in three combined studies following the launch of Eklira® in the UK. This first study involves characterising patients prescribed aclidinium bromide from tiotropium, and determining how many patients are satisfied with their change to aclidinium therapy. This will determine the acceptability of aclidinium in clinical practice.

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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

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**Study contact**

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**Primary lead investigator**

Lim Daina

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 26/09/2013

Actual: 26/09/2013

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**Study start date**

Planned: 01/10/2013

Actual: 01/10/2013

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**Data analysis start date**

Planned: 02/06/2014

Actual: 13/05/2014

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**Date of final study report**

Planned: 29/08/2014

Actual: 06/10/2014

## Sources of funding

- Pharmaceutical company and other private sector

- Other

## More details on funding

Almirall, Research in Real Life

## Study protocol

[2014\\_05\\_19\\_\(R03712a\) Almirall Eklira study 1 protocol-v2\\_ENCEPP.pdf](#) (155.71 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

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**Study type:**

**Scope of the study:**

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To evaluate the real-life effectiveness of the antimuscarine bronchodilator aclidinium bromide (Eklira®) as part of a three-staged study following the launch of Eklira® in the UK. This first study involves characterising patients prescribed aclidinium bromide from tiotropium and determine the acceptability of aclidinium by determining how many patients are satisfied with their change to aclidinium.

## 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 with COPD who changed their therapy from tiotropium to aclidinium bromide following its launch in the UK

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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

Other

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### Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

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### Estimated number of subjects

100

## Study design details

### Outcomes

The primary outcome for this study is the acceptability of change from tiotropium to aclidinium during the six-month outcome period. This is defined as the percentage of the patients changed to aclidinium bromide (received a prescription for aclidinium at date of first prescription) who did not receive  $\geq 1$  prescription for tiotropium during the outcome period. To provide real-world

data on the utilisation of acclidinium bromide in clinical practice, the patients prescribed acclidinium bromide will be characterised following in the year prior to acclidinium bromide initiation. As the study aims to characterise the patients who are prescribed acclidinium, all patients will be characterised regardless of whether or not they change back to tiotropium.

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### **Data analysis plan**

Summary statistics will be produced for all baseline variables. 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) For categorical variables, the summary statistics will include: • Sample size (n) • Count and Percentage by category (distribution). Plots will be produced for all baseline variables. For variables measured on the interval or ratio scale, these will include: • Frequency plots • Box and whisker plots The data will be prepared for analysis by: • Investigating potential outliers, • Identifying and creating new variables as necessary: o Transformations of skewed data (for example, log transformations), o Categorisation of heavily skewed data, • Investigating missing data (type of and reason for missingness).

## **Documents**

### **Study results**

[REG\\_SUMMIT\\_abstract\\_FINAL\\_eklira\\_2014\\_11\\_14.pdf](#) (68.28 KB)

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### **Study publications**

[Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying progn...](#)

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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 \(EHR\)](#)

## 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

## Data characterisation



**Data characterisation conducted**

No