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

PURI
https://redirect.ema.europa.eu/resource/8872

EU PAS number
EUPAS6573

Study ID
8872

DARWIN EU® study
No

Study countries
United Kingdom

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.

Study status
Finalised

Research institution and networks

Institutions

Research in Real Life
First published: 01/02/2024
Last updated 01/02/2024
Institution

Contact details

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Study contact

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Study timelines

Date when funding contract was signed
Planned:
26/09/2013
Actual:
26/09/2013

Study start date
Planned:
01/10/2013
Actual:
01/10/2013

Data analysis start date
Planned:

02/06/2014
Actual:
13/05/2014

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

Study type:
Non-interventional study

Scope of the study:
Disease epidemiology
Drug utilisation
Effectiveness study (incl. comparative)

Data collection methods:
Secondary data collection

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 acceptabily of aclidinium by determining how many patients are satisfied with their change to aclidinium.

Study drug and medical condition

Name of medicine
Eklira

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

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
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 ?1 prescription for tiotropium during the outcome period. To provide real-world data on the utilisation of aclidinium bromide in clinical practice, the patients prescribed aclidinium bromide will be characterised following in the year prior to aclidinium bromide initiation. As the study aims to characterise the patients who are prescribed aclidinium, all patients will be characterised regardless of whether or not they change back to tiotropium.

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,• Indentifying 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)

Study publications
Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying progn…

Data management

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

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No