Aclidinium Bromide Drug Utilisation Post-Authorisation Safety Studies (DUS): Common Protocol for Aclidinium (DUS1) and Aclidinium/Formoterol Fixed-Dose Combination (DUS2)

First published: 15/05/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6559

Study ID

39222

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Germany

United Kingdom

Study description

Aclidinium bromide is a long-acting antagonist of lung M3 receptors used as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. For a post-authorization safety study, a multinational database drug utilisation study (DUS1) in a cohort of new users of aclidinium bromide and new users of other inhaled medications frequently used by patients with COPD will be implemented. DUS2 will begin when the fixed-dose combination of aclidinium bromide/formoterol fumarate becomes available. DUS1/DUS2 objectives are: • To describe the characteristics and patterns of use of new users of aclidinium bromide (monotherapy or in combination with formoterol) and new users of other COPD medications. • To evaluate the potential off-label use of aclidinium bromide • To describe users of aclidinium bromide in subgroups of patients for whom there is missing information in the RMP • To establish a core cohort of new users of aclidinium bromide for the future evaluation of safety concerns described in the RMP The study is planned in the Clinical Practice Research Datalink, the German Pharmacoepidemiological Database, and the national health databases in Denmark. DUS1/DUS2 are non-interventional cohort studies of new users of aclidinium bromide (monotherapy or in combination, respectively), tiotropium, LABA, and LABA+ICS who will be characterised 1) at the index date according to prior clinical information and prior and concurrent use of medications and 2) during the year following the index date to assess patterns of use. All available new users of aclidinium bromide or of the fixed-dose combination of aclidinium/formoterol at study initiation in each database will be included. The estimated study target is 1,500-2,000 new users of aclidinium bromide (for DUS1,the fixed-dose combination of aclidinium/formoterol for DUS2) and a sample of 2,000 new users of each comparator in each country-specific database.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

First published: 21/04/2010

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Institution | Not-for-profit | ENCePP partner

Multiple centres: 3 centres are involved in the study

Contact details

Study institution contact

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Study contact

crebordosa@rti.org

Primary lead investigator

Cristina Rebordosa

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/12/2013

Actual: 10/01/2014

Study start date

Planned: 30/06/2015

Actual: 06/07/2015

Data analysis start date

Planned: 14/07/2015

Actual: 26/08/2015

Date of interim report, if expected

Planned: 31/03/2017

Actual: 18/05/2017

Date of final study report

Planned: 29/05/2020

Actual: 12/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Almirall, S.A./AstraZeneca AB

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

D6560R00005 (DUS1 - Eklira), and D6570R00002 (DUS2- Duaklir)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Describe characteristics and patterns of use of new users of aclidinium bromide and other selected COPD treatments,Evaluate potential off-label use of aclidinium bromide,Describe users of aclidinium bromide in subgroups of patients for whom there is missing information in RMP,Establish a core cohort of new users of aclidinium bromide for future evaluation of safety concerns described in RMP

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03AC12) salmeterol

salmeterol

(R03AC13) formoterol

formoterol

(R03AC18) indacaterol

indacaterol

(R03AK06) salmeterol and fluticasone

salmeterol and fluticasone

(R03AK07) formoterol and budesonide

formoterol and budesonide

(R03AK07) formoterol and budesonide

formoterol and budesonide

(R03AL05) formoterol and aclidinium bromide

formoterol and aclidinium bromide

(R03BB04) tiotropium bromide

tiotropium bromide

(R03BB05) aclidinium bromide

aclidinium bromide

(R03BB06) glycopyrronium bromide

glycopyrronium bromide

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

New users of aclidinium bromide (on monotherapy or with concomitant use of formoterol) and new users of other COPD medications will be identified and included in the specific exposure cohort of interest.

Inclusion Criteria

Patients in the study will be required to meet the following criteria, as ascertained from

each of the automated databases:

- To have at least 1 year of enrolment in the database (DUS1 and DUS2).
- To have not been prescribed aclidinium bromide as monotherapy or with concomitant use of formoterol during the 6 months before the date of first prescription of aclidinium bromide (index date) in DUS1
- To have not been prescribed aclidinium bromide as monotherapy, with concomitant use of formoterol, or as aclidinium/formoterol during the 6 months before the date of first prescription of aclidinium bromide (index date) in DUS2

Exclusion Criteria

No age restrictions or exclusion criteria will be applied. This will allow for the characterisation of all users of aclidinium bromide and comparator drugs irrespective of the indication for which these medications are used. Identification of potential off-label use of aclidinium bromide in the paediatric and adult populations is one of the specific objectives of this DUS.

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

Hepatic impaired

Renal impaired

Estimated number of subjects

22500

Study design details

Data analysis plan

The analysis will be descriptive and implemented in two phases:Phase 1. Baseline analysis: • Age and sex distribution of users • Proportion of patients with the above listed characteristics, comorbidities, and comedications for up to 1 year before the index date. • Proportion and description of patients with off-label use.Phase 2. Follow-up analysis: • Assessment of relevant comorbidities, pregnancies, and treatment patterns (duration, dose, and switching patterns) during 1 year after the index date.

Documents

Study publications

Rivero-Ferrer E, Witzleb AJ, Olesen M, Plana E, Aguado J, Saigi-Morgui N, Rubin…

Plana E, Rebordosa C, Aguado J, Thomas S, Garcia-Gil E, Perez-Gutthann S, Caste…

Rebordosa C, Rubino A, Witzleb AJ, Olesen M, Plana E, Aguado J, Saigi N, Daoud …

Rebordosa C, Varas-Lorenzo C, Castellsague J, Plana E, Bui C, Aguado J, Garcia …

Rebordosa C, Plana E, Aguado J, Thomas S, Garcia-Gil E, Perez-Gutthann S, Caste…

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 source(s)

Clinical Practice Research Datalink

German Pharmacoepidemiological Research Database

Data source(s), other

National Health Databases Denmark

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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