Drug Utilisation Study for Olodaterol

First published: 24/01/2017

Last updated: 14/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17386

Study ID

33210

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ France
- ☐ Netherlands

Study description

Boehringer Ingelheim GmbH (BI) developed olodaterol, an inhaled long-acting beta2-agonist (LABA), for the indication of chronic obstructive pulmonary

disease (COPD). Because the use of LABAs has been associated with increased morbidity and mortality in patients with asthma, the health authorities requested the conduct of a post-approval drug utilisation study to assess potential off-label use of olodaterol in asthma and to characterise the use of olodaterol in clinical practice. The single agent indacaterol, the only other marketed LABA authorised in clinical practice for COPD but not for asthma, will also be assessed. Study objectives include the following: (1) Quantify the frequency of off-label use of olodaterol and indacaterol among new users of these medications, and (2) Describe the baseline characteristics of new users of olodaterol and indacaterol. This cross-sectional study will use information among new users of olodaterol or indacaterol collected in the following healthcare databases: the PHARMO Database Network in the Netherlands, the National Registers in Denmark, and the IMS Health Information Solutions (IMS) Real-World Evidence (RWE) Longitudinal Patient Database (LPD) in France. The source population is all subjects enrolled in the selected study databases at the date olodaterol became available in each database's country. The study groups are those subjects from the source population who receive a first dispensing for single-agent formulations of olodaterol for the primary objective or indacaterol for the secondary objective and have at least 12 months of continuous enrolment in the study databases. The study will describe the number and proportion of new users by indication and potential off-label use and according to medical history and use of co-medications.

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

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Real World Evidence Solutions, IMS Health

- [ ] France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

- [ ] Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Alicia Gilsenan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/08/2015

Actual: 18/08/2015

Study start date
Planned: 01/02/2017

Actual: 12/01/2017

Data analysis start date
Planned: 08/02/2017

Date of interim report, if expected
Planned: 01/09/2017

Actual: 23/08/2017

Date of final study report
Planned: 30/09/2018

Actual: 03/09/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim International GmbH

Study protocol

Olodaterol DUS Protocol_Redacted.pdf(605.23 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

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:

To quantify the frequency of off-label use of olodaterol among new users of these olodaterol and indacaterol (i.e. the proportion of new users who do not

have COPD) and to describe the baseline characteristics of new users of olodaterol.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03AC18) indacaterol

indacaterol

(R03AC19) olodaterol

olodaterol

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

All subjects enrolled in the selected study databases at the date olodaterol became available in each database’s country. The study groups are those subjects from the source population who receive a first dispensing for single-agent formulations of olodaterol for the primary objective or indacaterol for the secondary objective and have at least 12 months of continuous enrolment in

the study databases.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

Estimated number of subjects

20000

Study design details

Outcomes

The primary outcome is the prevalence of off-label prescribing among new users of olodaterol. The secondary outcome is the prevalence of off-label prescribing among new users of indacaterol.

Data analysis plan

Statistical analyses will be descriptive in nature. Descriptive statistics will include the absolute and relative number of subjects, mean, median, standard deviation, and range for continuous variables. Statistical inference will not be performed (e.g. no P values will be generated). Where appropriate, two-sided 95% confidence intervals will be presented. All analyses will be conducted

separately in each study database and will be further analysed separately by new users of olodaterol and by new users of indacaterol, further stratified by treatment-naïve subjects and switchers. In the French IMS RWE LPD, data will be analysed separately for the panel of general practitioners and for the panel of pulmonologists. Analysis for each report (i.e. interim and final) will include data on all patients starting treatment with olodaterol or indacaterol from the start of such treatment up to the latest available data.

Documents

Study results

1222_53_Olodaterol DUS_Final Report_Final_20Aug2018_clean_Abstract (pages 6 to 13)_Redacted.pdf(234.13 KB)

Study publications

Rebordosa, C., Houben, E., Laugesen, K. et al. No Evidence of Off-label Use of …

Rebordosa C, Houben E, Laugesen K, Asmar J, Montonen JT, Aguado J, et al. Utili…

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)

Danish registries (access/analysis)

PHARMO Data Network

Longitudinal Patient Data - France

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