Comparative effectiveness and safety of Ipramol (ipratropium/albuterol) SteriNebs® vs. DuoNeb®

First published: 23/10/2014

Last updated: 21/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7753

Study ID

9095

DARWIN EU® study

No

Study countries

United States

Study description

Historic cohort, US database study comparing effectiveness and safety of nebulised COPD medication labelled by Teva Ltd (Ipramol SteriNebs®) against the originator product (DuoNeb®)

Study status

Finalised

Research institutions and networks

Institutions

Research in Real Life

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rafael Mares

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 07/05/2014

Actual: 07/05/2014

Study start date
Planned: 30/06/2014

Actual: 07/07/2014

Data analysis start date
Planned: 15/08/2014

Actual: 19/09/2014

Date of interim report, if expected
Planned: 14/10/2014

Actual: 14/10/2014

Date of final study report
Planned: 03/11/2014

Actual: 03/11/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva

Study protocol

R05113_Ipramol_Sterinebs_Protocol_V03.pdf (551.77 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim of this study is to compare Ipramol SteriNebs® with its originator, DuoNeb®. The primary objective is to assess whether effectiveness (in terms ofexacerbations) of Ipramol SteriNebs® is non-inferior to that of DuoNeb®.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Historical cohort database study

Study drug and medical condition

Medicinal product name, other

Ipramol Sterinebs, Duoneb

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Chronic obstructive pulmonary disease (COPD) patients aged ≥ 35 years who had ≥ 1 prescription for either Ipramol SteriNebs® or DuoNeb® at IPD and at least two years of continuous data (1 year prior and 1 year post IPD)

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

2142

Study design details

Outcomes

The primary outcome of this study is "effectiveness", evaluated in terms of:1. Severe COPD exacerbations (hospitalisations) in outcome period, and2. Moderate and severe COPD exacerbations in outcome period(Please see the attached protocol for full definitions of these outcomes), The secondary

outcome of this study is "safety", evaluated in terms of: Adverse Events (AEs). These will include AEs known to be related to Ipramol SteriNebs® and DuoNeb®, as specified in their respective summary of product characteristics. (Please see the attached protocol for detailed definition of this outcome)

Data analysis plan

Statistically significant results will be defined as $p<0.05$ and trends as $0.05<p<0.10$. Summary statistics will be produced for all baseline and outcome variables by therapy. Treatment groups will be compared using t-test / Mann-Whitney U test (depending on distribution) for variables measured on the interval/ratio scale and using a chi square test for categorical variables.Outcomes analyses: patients may be matched on demographics and key measures of disease severity to minimise confounding, using random selection process through SAS statistical software to avoid selection bias. Effectiveness and safety in the outcome period will be compared between treatment groups using a conditional Poisson regression model. The model will use empirical standard errors (for more conservative confidence interval estimations) and adjustments will be made for potential baseline confounders. The adjusted rate ratio with 95% confidence interval will be reported.

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), other

Clinformatics™ Data Mart (CDM) United States

Data sources (types)

Administrative healthcare records (e.g., claims)

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