Comparative effectiveness and safety of Salbutamol Sterinebs® vs Ventolin Nebules® in COPD patients.

First published: 09/10/2014

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Study Ongoing

Administrative details

EU PAS number

EUPAS7645

Study ID

26285

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Historic cohort, UK database study comparing effectiveness and safety of nebulised medication labelled by TEVA Ltd (Salbutamol SteriNebs®) against the originator product (Ventolin Nebules®), in patients who received a diagnosis for COPD

Study status

Ongoing

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

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Institution **Educational 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

David Price

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: 30/06/2014

Data analysis start date

Planned: 15/08/2014

Actual: 19/08/2014

Date of interim report, if expected

Planned: 26/09/2014

Actual: 26/09/2014

Date of final study report

Planned: 03/11/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

TEVA Ltd

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

The aim of this study is to compare Salbutamol SteriNebs® with its originator, Ventolin Nebules®. The primary objective is to assess whether effectiveness of Salbutamol SteriNebs® is non-inferior to that of Ventolin Nebules®.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Historical cohort database study

Study drug and medical condition

Name of medicine, other

Salbutamol Sterinebs, Ventolin Nebules

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

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)

Estimated number of subjects

9273

Study design details

Outcomes

Primary outcome of this study is “effectiveness”, evaluated in terms of: (1) Severe COPD exacerbations (hospitalisations) in the outcome period, and(2) Moderate and severe COPD exacerbations in the outcome period. Please see the attached protocol for full definitions of these outcomes, Secondary outcome of this study is “safety”, evaluated in terms of Adverse Events (AEs). These will include AEs known to be related to Salbutamol SteriNebs® and Ventolin Nebules®, as specified in their respective summary of product characteristics. Please see the attached protocol for a fuller definition of this outcome.

Data analysis plan

Statistically significant results will be defined as $p<0.05$ and trends as $0.05\leq p<0.10$Summary statistics will be produced for all baseline and outcome variables, as a complete dataset and 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 outcomes 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

Data sources

Data source(s), other

Optimum Patient Care research Database United Kingdom

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