COMPARATIVE EFFECTIVENESS AND SAFETY OF BUDESONIDE STERINEBS® VS. PULMICORT RESPULES® IN A US POPULATION OF ASTHMA PATIENTS.

First published: 14/10/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7678

Study ID

26273

DARWIN EU® study

No

Study countries

☐ United States

Study description

Historic cohort, US database study comparing effectiveness and safety of nebulised medication labelled by TEVA Ltd (Budesonide SteriNebs®) against the originator product (Pulmicort Respules®), in patients with a diagnosis for asthma.

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

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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: 07/07/2014

Data analysis start date

Planned: 15/08/2014

Actual: 22/08/2014

Date of interim report, if expected

Planned: 26/09/2014

Actual: 26/09/2014

Date of final study report

Planned: 03/11/2014

Actual: 31/10/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

TEVA Ltd

Study protocol

R04913_Budesonide Sterinebs_Protocol v04.pdf(637.77 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 Budesonide SteriNebs® with its originator, Pulmicort Respules®. The primary objective is to assess whether effectiveness (in terms of exacerbations) of Budesonide SteriNebs® is non-inferior to that of Pulmicort Respules® in both adult and children diagnosed with asthma.

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

Budesonide Sterinebs, Pulmicort Respules

Medical condition to be studied

Asthma

Population studied

Short description of the study population

People who have been diagnosed with asthma and have been prescribed Pulmicort Respules®. Patients must meet the following criteria:

1. Aged 1-80 years

Adult population: 12-80 years

Paediatric population: ≥1 and <12 years

2. Diagnosis for asthma (at any time), based on ICD9 codes (Annex 1)

3. Change sub-cohort: ≥1 prescription for Pulmicort Respules® in baseline (1 year prior to IPD) and ≥1 prescriptions for Budesonide SteriNebs® at IPD

4. Continuing sub-cohort: ≥1 prescription for Pulmicort Respules® during baseline (1 year prior to IPD) and ≥1 continued prescription for Pulmicort Respules® at IPD

5. Initiation sub-cohorts: no prescriptions for ICS nebulisers in baseline (1 year prior to IPD) and ≥1 prescription for either Budesonide SteriNebs® or Pulmicort Respules® at IPD

Age groups

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)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

13019

Study design details

Outcomes

Primary outcome of this study is "effectiveness", evaluated in terms of:(1) Asthma-related hospitalisation rate in the outcome period, and(2) Severe exacerbation (ATS/ERS definition) rate 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 Budesonide SteriNebs® and Palmicort Respules®, as specified in their respective summary of product characteristics. Please seethe 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 ofdisease severity to minimise confounding, using random selection process through SASstatistical software to avoid selection bias.Effectiveness and safety outcomes in the outcome period will be compared betweentreatment groups using a Conditional Poisson regression model. The model will useempirical standard errors (for more conservative confidence interval estimations) andadjustments 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

Clinformatics™ Data Mart (CDM) database 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

Unknown