Real-life effectiveness evaluation of budesonide/formoterol (BF) Spiromax for the management of asthma and COPD

First published: 21/04/2016

Last updated: 29/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17275

EU PAS number

EUPAS13238

Study ID

17275

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Four complimentary post-marketing retrospective observational studies to evaluate the real-life effectiveness and cost-effectiveness of BF Spiromax and to characterise patients prescribed BF Spiromax in the two years following product launch in the United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

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

Jaco Voorham

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/03/2015

Actual: 20/03/2015

Study start date

Planned: 16/09/2015

Actual: 16/09/2015

Data analysis start date

Planned: 09/05/2016

Date of interim report, if expected

Planned: 29/01/2016

Actual: 29/01/2016

Date of final study report

Planned: 03/02/2017

Actual: 16/01/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva Pharmaceutical Industries

Study protocol

160301_R00615_Spiromax_Protocol_V3.0.pdf(1.22 MB)

Regulatory

Was the study required by a regulatory body?

No

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:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To characterise patients who change to BF Spiromax from another FDC ICS/LABA and evaluate acceptability, and the real-life effectiveness and cost-effectiveness of BF Spiromax.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Spiromax, Symbicort Turbohaler, Seretide Accuhaler

Medical condition to be studied

Asthma

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Adult Asthma and COPD patients who were on either Symbicort® Turbohaler® or Seretide® Accuhaler® during their baseline period and received a continued prescription for same inhaled corticosteroid (ICS)/long-acting β2 agonist (LABA) FDC or were changed to DuoResp® Spiromax®.

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

Asthma and Chronic obstructive pulmonary disease patients

Estimated number of subjects

6400

Study design details

Outcomes

Risk Domain Control (binary), Comparison of severe exacerbation rate, treatment stability, SABA usage, and lower respiratory-related hospitalisations.Cost-effectiveness in relation to asthma- and COPD-related total and disaggregated respiratory therapy prescription costs, primary care

consultation costs, and respiratory-related hospitalisation costs.

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, for each study phase cohort. In phase 4, patients will be uniquely matched on demographics and key measures of disease severity to minimise confounding. Matching variables will be selected based on clinical review and baseline differences between the treatment groups. Matching will be conducted separate for asthma and COPD patients. The primary outcome will be analysed using conditional logistic regression, separately for asthma and COPD patients. Secondary outcomes will be analysed using conditional poisson, logistic, and ordinal logistic regression as appropriate, separately for asthma and COPD patients.

Documents

Study results

170116_R00615_Spiromax_ph34_final_report_V1_3.pdf(4.41 MB)

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

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

Unknown