Exploratory study identifying the benefits of pMDI versus Diskus for delivering fluticasone/salmeterol combination therapy in patients with chronic obstructive pulmonary disease (COPD)

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/8830

EU PAS number
EUPAS7072

Study ID
8830

DARWIN EU® study
No

Study countries
United Kingdom

Study description
The aims of this exploratory study are to characterise patients with chronic obstructive pulmonary disease (COPD) initiating with fluticasone/salmeterol combination therapy delivered via pressurised metered dose inhaler (pMDI, also known as Evohaler) or Diskus (also known as Accuhaler), and to identify and compare the potential benefits of using either device in the delivery of fluticasone/salmeterol combination therapy in terms of both efficacy and adverse events, in particular:a. Number of COPD exacerbationsb. Development of pneumonia infections c. Type II diabetes diagnosisd. Therapeutic index e.

Number of severe COPD-related events, including: i. Lower respiratory tract infectionsii. Oral thrush

Study status
Ongoing

Research institution and networks

Institutions

Research in Real Life
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Institution

Contact details

Study institution contact
David Price
Study contact

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Primary lead investigator
Jessica Martin
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
12/12/2013

Study start date
Actual:
14/03/2014

Data analysis start date
Actual:

13/05/2014

Date of final study report
Planned:
01/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mundipharma

Study protocol

R01913_Protocol_Seretide Diskus vs MDI COPD study_Mundipharma_091014_v3.pdf
(558.97 KB)

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 type:
Non-interventional study

Scope of the study:
Effectiveness study (incl. comparative)
Safety study (incl. comparative)

Main study objective:
(1) Characterising patients with COPD on fluticasone/salmeterol combination therapy via pMDI and Diskus.(2) Identifying and comparing the potential benefits of using pMDI versus Diskus in the delivery of fluticasone/salmeterol combination therapy in terms of both efficacy and adverse events.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine, other
Seretide Evohaler, Seretide Accuhaler

Medical condition to be studied
Chronic obstructive pulmonary disease
Pneumonia
Diabetes mellitus
Oral candidiasis
Lower respiratory tract infection

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
5000

Study design details

Data analysis plan
Statistically significant results will be defined as p<0.05 and trends as 0.05?p<0.10Summary statistics will be produced for all baseline and outcome variables, as a complete dataset and by device. For variables measured on the interval or ratio scale, these will include:Sample size (n) & percentage non-missingMean & Variance / Standard DeviationRange (Minimum / Maximum)Median & Inter-quartile Range (25th and 75th percentiles)For categorical variables, the summary statistics will include:Sample size (n)Range (if applicable)Count and Percentage by category (distribution)Treatment arms 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.

Data management

Data sources

Data source(s), other
OPCRD 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