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

First published: 09/10/2014

Last updated: 21/02/2024

Study Ongoing

Administrative details

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 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

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

Medicinal product name, 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

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

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