Characterising patients and examining real-life outcomes for UK patients with COPD initiating on or changing to Fostair (REACH II)

First published: 13/04/2015

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9142

Study ID

26266

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Two-stage historical cohort study to evaluate, in a comparative effectiveness study, whether Fostair pMDI is non-inferior, in terms of COPD exacerbation prevention, to other fixed dose combination (FDC) inhaled corticosteroid (ICS) / long-acting beta agonist (LABA) COPD therapies.

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

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/02/2015

Actual: 10/02/2015

Study start date

Planned: 07/04/2015

Actual: 07/04/2015

Data analysis start date

Planned: 20/04/2015

Actual: 20/04/2015

Date of interim report, if expected

Planned: 01/09/2017

Actual: 01/09/2017

Date of final study report

Planned: 11/09/2015

Actual: 05/09/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Chiesi Ltd

Study protocol

Protocol for REACH II 100415 B&W.pdf (1.24 MB)

R02813 REACH II Stage 2 protocol V1.2.pdf (915.57 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 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 evaluate whether beclomethasone/formoterol (Fostair pMDI) is non-inferior in terms of COPD exacerbation prevention, to other fixed dose combination inhaled corticosteroid/long-acting beta agonist COPD therapies.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Historical cohort database study

Study drug and medical condition

Medicinal product name, other

Fostair pMDI

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Clinician diagnosed COPD (confirmed by spirometry: FEV1/FVC <0.7); Age ≥35 years at index date; Two years of continuous practice data comprising 1-year baseline data and 1-year outcome data; ≥2 prescriptions of the same licensed FDC ICS/LABA (including the prescription on index date) during the outcome period [Fostair® pMDI, Seretide® 500 Accuhaler®, Symbicort® 200 Turbohaler®, and Symbicort® 400 Turbohaler®]; ≥1 prescription of LABA and/or LAMA (with or without an ICS alone) and/or a FDC ICS/LABA therapy during a 2-year period prior to the index date; ≥1 moderate to severe COPD exacerbation during an 18-month period preceding index date OR ≥1 moderate to severe COPD exacerbation preceding index date ever; FEV1 <55% predicted recorded ever.

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

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

80000

Study design details

Outcomes

The proportion of patients with no COPD exacerbations in the outcome period. Respiratory outcomes for Fostair pMDI relative to other COPD therapies considered (please see full protocol for details) and cost-effectiveness outcomes for Fostair pMDI relative to other COPD therapies considered (please see full protocol for details)

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 SAS statistical software to avoid selection bias.To show non-inferiority in exacerbation prevention, the adjusted proportions of patients within each treatment group, recording no exacerbations in the outcome period will be calculated using a generalised linear model with binomial distribution and logit link.95% confidence interval will be reported.

Documents

Study results

20170821_R02813 REACH II Stage 2finalreportl V1.3.pdf (2.9 MB)

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

Optimum Patient Care Research Database (OPCRD)

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