COMParative clinical effectiveness of FostAIR (extrafine beclomethasone/formoterol) as maintenance and reliever therapies in adult patients with asthma (CompAIR)

First published: 21/11/2024

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000377

EU PAS number

EUPAS1000000377

Study ID

1000000377

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A non-inferiority study using a retrospective cohort design to compare people taking Fostair and Symbicort as maintenance and reliever therapy (MART). The study will use the Optimum Patient Care Research Database (OPCRD) to identify adults (≥18 years) with a diagnosis of asthma and no other additional chronic respiratory condition who initiated Fostair or Symbicort as MART for the first time from July 2012 (i.e. when Fostair was first introduced). Index date will be the date of initiating Fostair or Symbicort with at least 12 months registration at the relevant GP surgery. Individuals will be propensity score weighted such that the chosen characteristics of the individuals are the same in each of the treatment groups. The primary outcome is non-inferiority of severe exacerbation rates in the 12 months following treatment initiation, as defined as inferiority of no more than 10% at the 2.5% (one-sided probability) level.

Study status

Ongoing

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

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Study timelines

Date when funding contract was signed

Actual: 06/09/2024

Study start date

Actual: 13/11/2024

Data analysis start date

Planned: 12/12/2024

Date of interim report, if expected
Planned: 31/12/2024

Date of final study report
Planned: 30/04/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CHIESI

Study protocol

Protocol_CompAIR_v2.2_20241119.pdf(935.18 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Primary data collection

Study design:

Historical cohort study using the Optimum Patient Care Research Database (OPCRD).

Main study objective:

Determine whether Fostair® is at least equivalent (non-inferior) to Symbicort® for MART for exacerbation prevention in adults with asthma.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Fostair

Study drug International non-proprietary name (INN) or common name

BECLOMETASONE DIPROPIONATE

FORMOTEROL FUMARATE DIHYDRATE

Anatomical Therapeutic Chemical (ATC) code

(R03AK08) formoterol and beclometasone

formoterol and beclometasone

Medical condition to be studied

Asthma

Population studied

Short description of the study population

The study will use the Optimum Patient Care Research Database (OPCRD) to identify adults (≥18 years) with a diagnosis of asthma and no other additional chronic respiratory condition who initiated Fostair or Symbicort as MART for the first time from July 2012 (i.e. when Fostair was first introduced). Index date will be the date of initiating Fostair or Symbicort with at least 12 months registration at the relevant GP surgery. Individuals will be propensity score weighted such that the chosen characteristics of the individuals are the same in each of the treatment groups.

Age groups

Adult and elderly population (≥18 years)

Special population of interest, other

People living with asthma

Estimated number of subjects

78938

Study design details

Setting

This is a historical cohort study using the Optimum Patient Care Research Database (OPCRD). The OPCRD is an electronic primary care record database covering more than 1,000 GP surgeries across England, Scotland, Wales and Northern Ireland.

Comparators

The study population (i.e. people taking Fostair) will be compared with people taking Symbicort using the same inclusion/exclusion criteria.

Outcomes

(1) Non-inferiority of severe exacerbation rates (primary aim), asthma control (secondary aim) and persistence (secondary aim) is defined as inferiority of no more than 10% at the 2.5% (one-sided probability).
(2) Overall asthma control
(3) Persistence
(4) Number and timing of SABA inhalers and total greenhouse gases associated with SABA

Data analysis plan

The baseline characteristics of the study (Fostair) and control (Symbicort) populations will be described in accordance with the inclusion/exclusion criteria before and after propensity score methods to balance characteristics. Binary outcomes (asthma control, persistence) will be compared using logistic regression and exacerbation rates using negative binomial regression. Estimates of greenhouse gas emissions will be derived from the number of SABA inhalers used and will be descriptive only.

Summary results

Preliminary findings from this study will be presented at the European Respiratory Society (ERS) Conference in February 2025. The work will be published in a peer-reviewed journal in August 2025.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Primary care data

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