FLAIR: Fostair vs Symbicort: CLinical effectiveness of anti-inflammatory reliever therapies (AIR): a non-inferiority study

First published: 30/04/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000560

Study ID

1000000560

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 anti-inflammatory reliever therapy (AIR). 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 AIR 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. Follow-up will be up to 3 years, allowing exposure time to vary as people exit the cohort (transferring out of GP practice or death). 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 2 years following treatment initiation, as defined as inferiority of no more than 20% at the 2.5% (one-sided probability) level.

Study status

Ongoing

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

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Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 13/03/2025

Actual: 13/03/2025

Study start date

Planned: 31/03/2025

Actual: 31/03/2025

Data analysis start date
Planned: 30/04/2025

Date of interim report, if expected
Planned: 02/06/2025

Date of final study report
Planned: 31/07/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Chiesi UK, OPRI UK

Study protocol

FLAIR Study Protocol_V3.0_28042025.pdf(1.45 MB)

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:

Human medicinal product

Study topic, other:

Asthma

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Healthcare resource utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Historical cohort study using the Optimum Patient Care Research Database (OPCRD) and inverse probability treatment weighting.

Main study objective:

Determine whether Fostair (pressurised metered dose inhaler [pMDI] or dry powder inhaler [DPI]) is comparable (non-inferior) to Symbicort (pMDI or DPI) as AIR in patients with asthma, based on the rate of asthma exacerbations over the 3-year follow-up period.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

FOSTAIR

SYMBICORT

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

BECLOMETASONE

FORMOTEROL

BUDESONIDE

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 AIR 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.

Patients will be followed up for up to 3 years.
As well as presence of other respiratory condition (e.g. COPD), patients will be excluded if they have >1 short-acting beta-agonist (SABA) prescription in the year after initiation of AIR (as this would indicate that the patient is not using the inhaler as AIR).

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest, other

People living with asthma

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)

(2) Non-inferiority of asthma control (secondary aim) – using the Royal College of Physician’s 3 Questions (RCP3Q) questionnaire completed at asthma visits

(3 Mean daily steroid (inhaled corticosteroids and oral corticosteroids) exposure and overall oral corticosteroid exposure

(4) Persistence (proportion switching)

(5) Healthcare utilisation (asthma-related primary care consultations; asthma-related accident & emergency admissions; asthma-related hospital admissions)

(6) Reliever (SABA) usage

(7) Safety (acute cardiovascular events)

Data analysis plan

The baseline characteristics of the Fostair and Symbicort populations will be described in accordance with the inclusion/exclusion criteria before and after propensity score balancing methods. Standardised mean differences (SMD) will be used to compare differences between characteristics of individuals in the study population and control population (any values of ≥0.1 will be used to denote imbalance between groups). Propensity scores for treatment with

Fostair (pMDI or DPI) vs Symbicort (pMDI or DPI) will be calculated based on their characteristics (sociodemographic, treatment, comorbidities and measurements). Inverse probability of treatment weights (IPTW) will be used in regression analyses to improve balance between the two groups.

The primary analysis will use Poisson regression (if overdispersion is not present) or negative binomial regression (if overdispersion is present) to compare relative exacerbation rates. The secondary outcomes will use logistic regression (asthma control), the t-test/Mann-Whitney U-test (mean ICS/OCS daily dose, OCS exposure); Chi-squared test (difference between two independent proportions; persistence); and Poisson/negative binomial regression (healthcare utilisation).

Non-inferiority will be declared if Fostair AIR is no more than 20% (relative) worse than Symbicort AIR at the 2.5% (one-sided) level of probability, shown by the relevant 95% confidence limit. This will be judged from the upper 95% confidence limit for the incidence rate ratio for exacerbations (primary aim), and from the lower 95% confidence limit for the odds ratio for overall asthma control (secondary aim). Additional aims will use descriptive statistics and will not use a priori non-inferiority margins.

Summary results

Findings from this work will be submitted to the Primary Care Respiratory Society (PCRS) and the BTS (British Thoracic Society) conference. Interim results will be presented in June 2025. The study report will be completed at the end of July 2026.

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

No