Effectiveness of Fostair® (ICS/LABA) vs. dual bronchodilation (LABA/LAMA) in COPD (FELICITI)

First published: 09/04/2019

Last updated: 21/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS29223

Study ID

31702

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Historical cohort study comparing effectiveness of Fostair® (ICS/LABA) against dual bronchodilation in frequently exacerbating patients with chronic obstructive pulmonary disease (COPD). The primary objective is to examine whether the effectiveness, in terms of reducing COPD exacerbations, of initiating Fostair® is non-inferior, with a non-inferiority margin of 15%, to that of dual bronchodilation (LAMA/LABA) in patients with COPD. The secondary objective is to study the potential heterogeneity of the comparative effectiveness driven by severity of COPD and blood eosinophil count.

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

jaco@opri.sg

Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/10/2018

Actual: 31/10/2018

Study start date

Planned: 03/04/2019

Actual: 03/04/2019

Data analysis start date

Planned: 24/04/2019

Actual: 24/04/2019

Date of interim report, if expected

Planned: 31/05/2019

Actual: 12/08/2019

Date of final study report

Planned: 31/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Chiesi Pharmaceuticals

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:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

Determine if treatment with beclometasone/formoterol (Fostair®) is non-inferior in terms of effectiveness, compared to LABA/LAMA treatment in frequently exacerbating COPD patients. Also, differential responses to Fostair® treatment across patient subgroup will be explored.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Fostair

Anatomical Therapeutic Chemical (ATC) code

(R03A) ADRENERGICS, INHALANTS

ADRENERGICS, INHALANTS

Medical condition to be studied

Chronic obstructive pulmonary disease

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

4000

Study design details

Outcomes

The rate of moderate/severe COPD exacerbations during the entire follow-up. a) Time to treatment failure, b) rate of acute respiratory events, c) rate of acute OCS course, d) rate of antibiotic courses for COPD, e) mMRC score within 18 months, f) time until first pneumonia

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Data analysis plan

Patients initiating Fostair or LAMA/LAMA will be identified, and the rate of exacerbations (plus other outcomes) will be determined during the follow-up period. Patients will be right-censored when an important treatment change occurs, or at the end of data availability. A set of confounding handling approaches will be evaluated, and the best one with regard to residual bias will be chosen. Direct matching, propensity score matching, direct+propensity score matching and inverse probability of treatment weighting are the candidate approaches. Bias potential as well as restriction of study population will be used to determine the optimal approach. Event rates during follow-up will be analysed using negative binomial regression, taking the follow-up

duration into account.

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)

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