# 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

**PURI**
https://redirect.ema.europa.eu/resource/31702

**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 institution and networks

## Institutions

**Observational & Pragmatic Research Institute Pte (OPRI)**
United Kingdom
**First published:** 06/10/2015
Last updated 23/11/2016

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**ENCePP partner**

# Contact details

**Study institution contact**
Jaco Voorham

**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

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**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

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**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

**Name of medicine, other**
Fostair

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**Anatomical Therapeutic Chemical (ATC) code**
(R03A) ADRENERGICS, INHALANTS

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**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)

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**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

**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

# 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