

Real life effectiveness and cost impact evaluation of fixed dose combination fluticasone propionate/formoterol (Flutiform®) compared to fluticasone propionate/salmeterol (Seretide®) (eFFectiveness)

First published: 02/03/2016

Last updated: 23/04/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS12631


Study ID

12632

DARWIN EU® study

No

Study countries

 United Kingdom

Study description

This study examines the effectiveness and cost impact of treatment with an inhaled corticosteroid/long acting beta agonist (ICS/LABA) either as fluticasone propionate/formoterol (FP/FOR) or fluticasone propionate/salmeterol (FP/SAL) in asthmatic patients extracted from the optimum patient care database (OPCD).


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: 01/01/2014

Actual: 30/03/2014

Study start date

Planned: 02/03/2015

Actual: 02/03/2016

Data analysis start date

Planned: 03/08/2015

Actual: 24/08/2015

Date of interim report, if expected

Planned: 17/03/2016

Actual: 01/03/2016

Date of final study report

Planned: 29/04/2016

Actual: 02/03/2016

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Napp, RIRL

Study protocol

[150519_R03212c_Napp_Flutiform_switch_study3_protocol_V2.0_AT.compressed.pdf](#)

(1.16 MB)

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 examine non-inferiority of effectiveness (in terms of 'no exacerbations' ATSE/ERS Task Force definition) of fluticasone propionate / formoterol (Flutiform®, FP/FOR) relative to fluticasone propionate / salmeterol (Seretide®, FP/SAL) in matched patients from two cohorts of patients with asthma

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

FLUTICASONE PROPIONATE

FORMOTEROL

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Adolescent and adult asthmatic patients who have received ≥ 2 fluticasone propionate/formoterol prescriptions during the outcome period for treatment groups exclusive of prescription at index date, or : ≥ 2 fluticasone propionate/salmeterol prescriptions for control groups exclusive of prescription at index date.

Age groups

- Adolescents (12 to < 18 years)
 - 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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Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

43504

Study design details

Outcomes

To evaluate whether asthma patients treated with FP/FOR are associated with a non-inferior proportion with no exacerbations when compared to asthma patients treated with FP/SAL, To evaluate comparative effectiveness and cost impact outcomes of fluticasone propionate / formoterol (Flutiform®, FP/FOR) relative to fluticasone propionate / salmeterol (Seretide®, FP/SAL) in matched patients from two cohorts of patients with asthma

Data analysis plan

Patients will be combined from two cohorts - those who initiated on a fixed dose combination ICS/LABA and those who change to FP/FOR or continue on FP/SAL. Patients will be matched on one year of baseline characteristics including age, gender, spirometry, exacerbations, rhinitis, smoking status and predicted peak flow. After matching, adjusted analysis was provided for the primary outcome (proportion of patients with no exacerbations). A difference of less than 3.5% of the lower 95% confidence interval between the comparator (FP/FLU) and the control (FP/SAL) was considered to be non-inferior. Additional secondary outcomes are compared as appropriate using odds ratios, rate ratios and conditional logistic regression. Cost impact was compared through assessment of lower respiratory related medication, lower respiratory resource use and the combined medication and resource use after matching.

Documents

Study results

[R03212c_Statistical_Report_v1.pdf](#) (1.21 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.

Conflicts of interest of investigators

[20160302_R03212conflictinterest.pdf](#) (95.86 KB)

Composition of steering group and observers

[20160302_R03212cSteering Committee.pdf](#) (107.4 KB)

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