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

PURI
https://redirect.ema.europa.eu/resource/12632

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 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
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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 topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Effectiveness study (incl. comparative)

Data collection methods:
Secondary data collection

Main study objective:
To examine non-inferiority of effectiveness (in terms of ‘no exacerbations’ ATS/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
SALMETEROL

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)

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

Conflicts of interest of investigators
20160302_R03212conflictofinterest.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