An observational evaluation of prescribing of fixed-dose combination inhaled corticosteroid / long-acting beta2-agonist (ICS/LABA): fluticasone propionate / formoterol (FP/FOR) and adverse events in routine primary care at 18-months and 36-months post launch

First published: 08/02/2016

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/31771

EU PAS number

EUPAS12330

Study ID

31771

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This study aims to evaluate adverse events, prescribing prevalence and patient characteristics for patients initiating on FP/FOR or other FDC ICS/LABA therapies prescribed in the 18 and 36 months post launch of FP/FOR in the UK. It will be a historical cohort study within which four subgroups will be evaluated (adult patients (≥ 12 years) with asthma, patients with COPD (and no asthma), paediatric asthma patients 4–11 years, patients prescribed ICS/LABA as the "MART" regimen). Patients included have ≥1 prescriptions for any ICS/LABA fixed-dose combination from 2012. The number and percentage of patients prescribed FP/FOR and other FDC ICS/LABAs and the frequency and percentage of adverse events and patient characteristics including demographic characteristics, comorbidities, medication and disease-severity measures will be evaluated for patients prescribed FP/FOR and other FDC ICS/LABA therapies, and for each of the subgroups.

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

Actual: 21/08/2014

Study start date
Planned: 19/02/2016

Actual: 24/06/2016

Date of final study report
Planned: 12/09/2016

Actual: 29/08/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mundipharma Research Ltd

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To quantify the prevalence of on and off-label prescribing of FP/FOR and other FDC ICS/LABA therapies.To evaluate adverse events in patients prescribed FP/FOR versus other FDC ICS/LABA therapies for both licensed and off-label groups.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Flutiform, Seretide, Symbicort, Fostair

Medical condition to be studied

Asthma

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients ≥4 years old captured in CPRD during the period from 25th September 2015 until 24th September 2015 (i.e. 36-months post UK launch of fluticasone propionate /formoterol (FP/FOR), where FP/FOR launch was on 25th September 2012) who initiated on any FDC ICS/LABA [including FP/FOR, fluticasone/salmeterol (FP/SAL), budesonide/formoterol (BUD/FOR), beclomethasone/formoterol (BDP/FOR)].

Age groups

Children (2 to < 12 years)

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

Other

Special population of interest, other

Asthma, Chronic obstructive pulmonary disease patients

Estimated number of subjects

3500

Study design details

Outcomes

Prevalence of on and off-label prescribing of FP/FOR and other FDC ICS/LABA therapies.Adverse events in patients prescribed FP/FOR versus other FDC ICS/LABA therapies for both licensed and off-label groups. Demographic, medication and disease-related characteristics for patients prescribed FP/FOR and other FDC ICS/LABA therapies.

Data analysis plan

Number of patients prescribed FP/FOR and each FDC ICS/LABA will be tabulated and detailed as a percentage of (a) all patients captured in CPRD during the time period 18/36-months post UK launch of FP/FOR and (b) each of the licensed/off-label subgroups.First occurrence of an adverse event per patient analysed: Annualised rate of each adverse event per 100 patients and time to each adverse event will be compared across FDC ICS/LABA therapies using Kaplan-Meier survival curves and, if appropriate, hazard ratios.Multiple occurrences of an adverse event per patient: Mean/median (as appropriate) number of each adverse event per patient.

Documents

Study results

160714_R02213_Flutiform offlabel and AEs_Stage 1_Final report_v2.0 (1).pdf (6.22 MB)

160829_R02213_Flutiform offlabel and AEs_Stage 2_Final report_v1.1 (1).pdf (5.12 MB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

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