Real-life effectiveness (and cost impact) evaluation of fixed-dose combination fluticasone propionate/formoterol (Flutiform®) for the management of asthma in a routine UK primary care population – Phase 2 (Real-life effectiveness of Flutiform - Phase 2)

First published: 16/10/2014

Last updated: 17/03/2015

Study Finalised

Administrative details

EU PAS number

EUPAS7641

Study ID

8885

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

To evaluate the comparative effectiveness of changing real-life asthma patients from fluticasone propionate / salmeterol (Seretide®, FP/SAL) to fluticasone propionate / formoterol (Flutiform®, FP/FOR) in asthma patients.

Study status

Finalised

Research institutions and networks

Institutions

Research in Real Life

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daina Lim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/07/2012

Actual: 25/07/2012

Study start date

Planned: 03/02/2014

Actual: 03/02/2014

Data analysis start date

Planned: 18/08/2014

Actual: 01/11/2014

Date of final study report

Planned: 28/11/2014

Actual: 31/12/2014

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Napp Pharmaceuticals, RIRL

Study protocol

2014_10_16 RiRL Study Protocol_phase2_ENCEPP.pdf(416.7 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the comparative effectiveness of changing real-life asthma patients from fluticasone propionate / salmeterol (Seretide®, FP/SAL) to fluticasone propionate / formoterol (Flutiform®, FP/FOR).

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Historical

Study drug and medical condition

Name of medicine, other

Seretide, Flutiform

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Patients aged 12-80 years who had evidence of active asthma, defined as a diagnostic code and/or ≥2 prescriptions for asthma therapy during the baseline year

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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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

154

Study design details

Outcomes

Co-primary outcomes1. Severe exacerbation rate (ATS definition)Defined as any of the following (outcome year):• Asthma-related hospital or emergency room attendance • Acute oral steroid prescriptions for asthma2. Composite proxy asthma control Defined as absence of the following (outcome year):• Severe exacerbations• Antibiotics prescriptions for LRTIs at a respiratory consultation, Secondary outcomes:1. ICS use – mean daily ICS dose2. Short-acting beta2agonist (SABA) use – mean daily SABA doseCost impact outcomes (optional)1. Asthma drug costs ± FDC ICS/LABA drug costs2. Cost of asthma resource utilisation3. Cost of asthma-related resource utilisation

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Data analysis plan

General Statistically significant results will be defined as $p<0.05$ and trends as $0.05 \leq p<0.10$. All analyses will be carried out using SPSS version 22 and Microsoft Office EXCEL 2013. Summary statistics Summary statistics will be produced for all baseline and outcome variables, as a complete dataset and for both baseline and outcome period. For variables measured on the interval or ratio scale, these will include: • Sample size (n) • Percentage non-missing • Mean • Variance / Standard Deviation • Range (Minimum / Maximum) • Median • Inter-quartile Range (25th and 75th percentiles) For categorical variables, the summary statistics will include: • Sample size (n) • Range (if applicable) • Count and Percentage by category (distribution)

Documents

Study results

2014_01_07_REG_SUMMIT_R03212b_FLUTIFORM_Phase2_FULL_FINAL_ver4.0_clean.pdf (74.35 KB)

Study publications

Aalbers R, Brusselle G, McIver T, Grothe B, Bodzenta-Lukaszyk A. Onset of bronc…

Bodzenta-Lukaszyk A, Dymek A, McAulay K, Mansikka H. Fluticasone/formoterol com…

Politiek MJ, Boorsma M, Aalbers R. Comparison of formoterol, salbutamol and sal…

Data management

Data sources

Data source(s), other

OPCRD United Kingdom

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