

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 1 (Real-life effectiveness of Flutiform® Phase 1)

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Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/8878>

EU PAS number

EUPAS4872

Study ID

8878

DARWIN EU® study

No

Study countries

United Kingdom

Study status

Finalised

Research institution and networks

Institutions

Research in Real Life

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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:

01/09/2012

Actual:

01/08/2013

Data analysis start date

Planned:

01/11/2013

Actual:

01/11/2013

Date of final study report

Planned:
31/01/2014
Actual:
31/01/2014

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Napp Pharmaceuticals, Resesarch in Real Life

Study protocol

[2014_01_28 RiRL Napp Study Protocol - Realworld Evaluation of Flutiform_version2_Phase1.pdf\(316.27 KB\)](#)

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:

Drug utilisation

Data collection methods:

Secondary data collection

Main study objective:

To evaluate the success 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

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Name of medicine, other

Flutiform, Seretide

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Asthma patients who had changed from fluticasone propionate / salmeterol (Seretide®; FP/SAL) to fluticasone propionate / formoterol (Flutiform®; FP/FOR)

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

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

100

Study design details

Outcomes

In this Phase 1 study, change success will be evaluated. Change success is defined as Percentage of FP/FOR patients who received ≥ 2 prescriptions of FP/FOR (i.e. ≥ 1 prescription in addition to that issued at IPD). If failed, the potential reasons for discontinuation will be evaluated including: (i) Occurrence of severe exacerbations within the 6-month period defined as: (ii) Loss of asthma control (in the subset of patients controlled at baseline) (iii) Adverse events

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 19.89, SAS version 9.3.910 and Microsoft Office EXCEL 2007. Summary statistics Summary statistics will be produced for all baseline and outcome variables, as a complete dataset and by treatment groups. 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

[IPCRG14LB-1326-v2_Final_submitted_edited.pdf](#) (115.71 KB)

Study, other information

[R03212a_PCRS abstract_Real world effectiveness Seretide_Napp_2014-06-06_FINAL submitted.pdf](#) (35.8 KB)

[R03212a_REG poster abstract_Real world effectiveness Flutiform_Napp_2014-06-06_FINAL.pdf](#) (36.75 KB)

Study publications

Global Initiative for Asthma

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

Masoli M, Fabian D, Holt S, Beasley R, Global Initiative for Asthma (GINA) Prog...

Demoly P, Gueron B, Annunziata K, Adamek L, Walters RD. Update on asthma contro...

Bahadori K, Doyle-Waters MM, Marra C, Lynd L, Alasaly K, Swiston J, FitzGerald ...

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Routine patient questionnaires

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