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)

First published: 28/01/2014

Last updated: 17/03/2015

Study Finalised

Administrative details

EU PAS number

EUPAS4872

Study ID

8878

DARWIN EU® study

No

Study countries

United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Research in Real Life

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Primary lead investigator

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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 use of data

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

GeneralStatistically 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 statisticsSummary 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

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.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Routine patient questionaires

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