# 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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**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

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**Study start date**
Planned: 01/09/2012

Actual: 01/08/2013

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**Data analysis start date**
Planned: 01/11/2013

Actual: 01/11/2013

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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

## 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