A Non interventional post authorisation study to determine the safety and effectiveness of flutiform® (Affirm Study). (FLT9503 AFFIRM)

First published: 06/06/2013

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/23261

EU PAS number

EUPAS4072

Study ID

23261

DARWIN EU® study

No

Study countries

- [ ] Czechia
- [ ] Denmark
- [ ] France
- [ ] Ireland
- [ ] Norway
- [ ] Slovakia
- [ ] Sweden
- [ ] United Kingdom

Study status

Ongoing

Research institutions and networks

Institutions

Bispebjerg and Frederiksberg Hospital

First published: 01/02/2024

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Institution

Department of Clinical Medicine,Section of Orthopaedics and Internal Medicine

Contact details

Study institution contact

Vibeke Backer

Study contact

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Primary lead investigator

Vibeke Backer

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 04/06/2013

Study start date

Planned: 02/09/2013

Actual: 20/11/2013

Date of interim report, if expected

Planned: 31/05/2016

Date of final study report

Planned: 31/08/2016

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 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

Evaluation of the safety of flutiform® in routine clinical practice by: Collection of data on the exposure to flutiform® and the frequency of adverse events.

Recording all adverse events reported spontaneously or after physicians’ open question by the subjects

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03AK07) formoterol and budesonide

formoterol and budesonide

(R03AK07) formoterol and budesonide

formoterol and budesonide

(R03AK09) formoterol and mometasone

formoterol and mometasone

Medical condition to be studied

Asthma

Population studied

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)

Estimated number of subjects

2500

Study design details

Data analysis plan

In general, continuous data will be summarised using the following descriptive statistics: n, mean, standard deviation, median, minimum and maximum. Two sided 95% confidence intervals will be presented around mean values where appropriate. Categorical data will be summarised as the number and percentage of subjects in each category.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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