The effect of flutiform® treatment on asthma control in patients with asthma in daily clinical practice; an observational study

First published: 20/10/2014

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Study Ongoing

Administrative details

EU PAS number

EUPAS7690

Study ID

15252

DARWIN EU® study

No

Study countries

☐ Belgium

Study description

To evaluate the effect of flutiform® treatment with respect to asthma control in patients with asthma in daily clinical practice.

Study status

Ongoing

Research institutions and networks

Institutions

Hôpital Erasme

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

Lies.delmulle@mundipharma.be

Primary lead investigator

Alain Michils

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 11/04/2014

Study start date
Actual: 28/02/2014

Date of final study report
Planned: 31/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mundipharma Comm VA

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To evaluate the effect of flutiform® treatment with respect to asthma control in patients with asthma in daily clinical practice

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03AK11) formoterol and fluticasone

formoterol and fluticasone

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

1200

Study design details

Outcomes

The primary efficacy endpoint will be defined as asthma control improvement after 6 months of flutiform® therapy (V3) and this compared to baseline V1. A change or difference in ACQ-score of 0.5 is the smallest that can be considered clinically important. To evaluate the asthma control and the absolute changes in ACQ-scores at each visit compared to baseline. The response to flutiform® therapy will be compared between patients with ICS alone as pre-treatment medication and patients with ICS + LABA as pre-treatment medication

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Data analysis plan

Continuous data will be summarized by their mean, standard deviation, 95% confidence interval of the mean, median, minimum and maximum. Categorical and ordinal data will be summarized by frequency and percentages. Where appropriate, 95% confidence intervals will be added.

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)

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