The effect of asthma pre-treatment on the efficacy of flutiform® treatment with respect to asthma control in patients with asthma in daily clinical practice; an epidemiologic study. (FLT9502)

First published: 02/05/2013

Last updated: 01/02/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS3889

Study ID

15240

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

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

Study status

Ongoing

Research institutions and networks

Institutions

Mundipharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Yvonne Van Megan info@contact-clinical-trials.com

Study contact

info@contact-clinical-trials.com

Primary lead investigator

Yvonne Van Megan

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 07/01/2013

Actual: 07/01/2013

Study start date
Planned: 07/01/2013

Actual: 07/01/2013

Data analysis start date
Planned: 01/05/2014

Actual: 01/05/2014

Date of final study report
Planned: 07/01/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mundipharma Pharmaceuticals BV

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:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

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

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Epidemiologic study

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

Study design details

Outcomes

To evaluate the effect of asthma pre-treatment on the efficacy of flutiform® treatment with respect to asthma control in patients with asthma in daily clinical practice. The primary efficacy endpoint will be defined as well controlled asthma (ACQ≤0.75,1) after 12 weeks of flutiform® therapy (V3). To evaluate the ‘ease of use’ of flutiform® treatment To evaluate the effect of flutiform® treatment on daily activities To assess compliance of flutiform® treatment To determine the patient preference of flutiform® treatment compared to previous asthma treatment in daily clinical practice To assess safety of flutiform® treatment

---

Data analysis plan

General This is an epidemiological study. Descriptive statistics of all efficacy parameters will be provided overall and by previous used asthma medication subgroup (ICS or ICS+LABA). Graphical data analysis will be used to visualize trends over time. Primary efficacy parameter The response on flutiform® treatment (ACQ≤0.75) at Visit 3 will be compared between the two pre-treatment groups, using logistic regression with pre-treatment group, asthma control at baseline and the interaction between pre-treatment and asthma control at baseline as covariates. The odds ratio and relative risk of response for patients pre-treated with ICS only relative to patients pre-treated with ICS and LABA will be presented with 95% confidence intervals. For the calculation of the relative risk modified Poisson regression will be used. Secondary efficacy parameters Asthma Control Ease of useDaily Activities

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)

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