Real-Life evaluation of asthma control and exacerbation risk in patients treated with fluticasone propionate / formotérol fixed-dose association (RealLiffe - FLT9507)

First published: 27/07/2016

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Study Ongoing

Administrative details

EU PAS number

EUPAS14418

Study ID

14419

DARWIN EU® study

No

Study countries

France

Study description

This is an open label, multi-centre non interventional study in approximately 1225 patients with asthma in 175 centres in France. The main objective of the study is to describe the proportion of patients with “well controlled” asthma according to the Asthma Control Questionnaire (ACQ) criteria after 6 months of treatment with Flutiform® 125µg/10µg or 50µg/5µg. The study consists of 2 visits: one at Baseline when Flutiform® is initiated and the second after 6 months of treatment. Eligible patients are to be treated and followed according to usual physician practice.

Study status

Ongoing

Research institutions and networks

Institutions

Mundipharma

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Institution

Contact details

Study institution contact

Laure Chayvialle linfo@contact-clinical-trials.com

Study contact

linfo@contact-clinical-trials.com

Primary lead investigator

Frederic de Blay

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/09/2015

Actual: 28/09/2015

Study start date

Planned: 28/09/2015

Actual: 28/09/2015

Data analysis start date

Planned: 01/12/2016

Date of final study report

Planned: 01/02/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mundipharma SAS

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:

Evaluate the proportion of patients with well-controlled asthma after 6 months treatment.

Study drug and medical condition

Medicinal product name, other

Flutiform

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)

Estimated number of subjects

1.225

Study design details

Outcomes

asthma control evaluation using Asthma Control Questionnaire (ACQ5), Describe the clinical, spirometric and therapeutic profiles of patients

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Data analysis plan

The socio-demographic characteristics of the physicians participating in the study will be described and compared with the national population of specialist physicians to evaluate the representativeness of the sample. Summary statistics (mean, standard deviation, median and quartiles) will describe quantitative variables, and frequencies and percentages will describe qualitative variables and missing data. Comparisons will be made by analysis of variance for quantitative data and by Chi2 tests for qualitative variables.

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