A prospective, multicentre, non-interventional study to collect further data on the safety and effectiveness of a new combination of formoterol and fluticasone in a pMDI with HFA 227 as the propellant, in subjects with mild to moderate-severe asthma. (FLT9501)

First published: 21/03/2013

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Study Ongoing

Administrative details

EU PAS number

EUPAS3702

Study ID

15258

DARWIN EU® study

No

Study countries

Germany

Study description

This non-interventional observational study was conducted to complement the results from randomized controlled trials by examining outcomes across the diverse spectrum of community-based patients with asthma. The parameter of interest are the safety and effectiveness of the new combination of fluticasone and formoterol (flutiform®) with HFA 227 as the propellant in patients with mild to moderate severe asthma in routine clinical practice. In this study the collection of data are the exposure to flutiform® and the evaluation of asthma control and the frequency of adverse events associated with flutiform® HFA 227 or which are known to be side effects of the treatment with other LABA/ICS combination drugs. The effectiveness evaluation will include the amount of rescue medication use, discontinuation due to lack of efficacy, flutiform® dose adjustment (step up, step down), amount of oral or parenteral corticosteroid use, asthma exacerbations and lung function parameters as reported by the patient or assessed during routine clinical practice at the physicians discretion. It is planned to observe 1500 patients in Germany in a time frame for one year.

Study status

Ongoing

Research institutions and networks

Institutions

Pneumologische Schwerpunktpraxis Kroker Schaeben Schmidt

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Institution

Contact details

Study institution contact

Birgit Langer-Brauburger info@contact-clinical-trials.com

Study contact

info@contact-clinical-trials.com

Primary lead investigator

Olaf Schmidt

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/10/2011

Actual: 31/10/2011

Study start date

Planned: 01/03/2012

Actual: 15/11/2012

Data analysis start date

Planned: 01/07/2015

Actual: 05/10/2015

Date of final study report
Planned: 31/05/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mundipharma GmbH

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:

Effectiveness study (incl. comparative)

Main study objective:

Evaluation of the safety and effectiveness (efficacy under real life conditions) of flutiform® in patients with asthma in routine clinical practice

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non interventional, observational 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

4000

Study design details

Data analysis plan

Continuous data will be summarised by using descriptive statistics – number of patients, mean, standard deviation, median, and range (minimum and maximum). Summary statistics and 95% 2-sided CIs will be used to estimate the effect based on a one sample t-test or ANCOVA especially for the secondary efficacy endpoints FEV1, FVC, FEV1/FVC and PEF. A safety analysis will be performed by descriptive methods on the safety population (SP). All adverse events will be analysed by its causal relationship to flutiform®. The number and percentage of patients reporting adverse events will be summarised by descriptive methods and 95% confidence intervals. In addition, adverse events by severity, adverse events leading to discontinuation of the observed medication and serious adverse events will be summarised. AEs of special

interest (e. g. cough, paradoxical bronchospasm, asthma worsening or serious asthma-related events) will beanalysed by descriptive methods and 95% confidence intervals.

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