Multicenter, open-label, non-interventional study to evaluate the impact on clinical effects, user-friendliness and patient's acceptance of Airflusal® Forspiro® in the treatment of asthma under real life conditions (ASSURE)

First published: 03/02/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12236

Study ID

28028

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Norway
- [ ] Sweden

Study description

Asthma is the single most common chronic disease among children, and also affects many adults. It is a significant public health problem and a high-burden disease for which prevention is partly possible and treatment can be effective. According to the international ERS/ATS guidelines on definition, evaluation and treatment of severe asthma, combination preparations of inhaled steroids and long-acting beta agonists – fixed combinations - have been firmly established treatments for bronchial asthma for years. With Airflusal® Forspiro® the proven combination of the steroid fluticasone (as propionate) and the long-acting beta agonist salmeterol (as xinafoate) is available in a newly developed inhaler. For successful therapy with inhaled pharmaceutical forms, it is essential for the inhalation technique to be correct. The non-interventional study ASSURE is firstly to assess the patients' asthma control and quality of life while using Airflusal® Forspiro® in everyday practice, when used for bronchial asthma according to the guidelines. Secondly, the study is to obtain information concerning patient acceptance and the user-friendliness of the new Forspiro® inhaler in normal conditions outside of clinical studies.

Study status

Finalised

Research institutions and networks

Institutions

Sandoz

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Institution

Multiple centres: 300 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Spencer Jones

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/02/2014

Actual: 24/02/2014

Study start date
Planned: 01/10/2014

Actual: 30/10/2014

Date of final study report
Planned: 30/06/2017

Actual: 03/08/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sandoz International GmbH

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 topic:

Disease /health condition

Human medicinal product

Medical device

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

To evaluate the impact on clinical effects, user-friendliness and patient's acceptance of Airflusal® Forspiro® in the treatment of asthma under real life conditions.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multicenter, open-label, non-interventional study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03AK06) salmeterol and fluticasone

salmeterol and fluticasone

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Patients with confirmed diagnosis of bronchial asthma and who were being treated with Airflusal® Forspiro®.

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)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

200

Study design details

Outcomes

Primary objectives- To find out about patients' own assessment of the control of their asthma (using the ACT)- To find out about any change in patients' quality of life. Secondary objectives- To assess patients' acceptance of Airflusal® Forspiro® Inhaler- To obtain information about manipulation and user-friendliness of the new Forspiro® inhaler.

Data analysis plan

All statistical evaluations will be descriptive. No confirmatory statistical tests will be performed. Exploratory comparisons of subgroups are planned as are transverse and longitudinal comparisons. P-values of statistical tests are descriptive and do not relate to testing hypotheses.

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

Unknown