ASSESSMENT OF THE EFFICACY OF COMBINATION THERAPY BUDESONIDE/FORMOTEROL FUMARATE (BUFOMIX EASYHALER 160/4.5 µG OR 320/9.0 µG PER INHALATION) IN PATIENTS DIAGNOSED WITH ASTHMA (ORN/AST/2016/004)

First published: 13/12/2016

Last updated: 31/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/22949

EU PAS number

EUPAS16451

Study ID

22949

DARWIN EU® study

No

Study countries

☐ Poland

Study description

This is a prospective non-interventional observational study of aproximately 2500 patients in Polish population receiving combination therapy bufomixeasyhaler - inhalation powder containing budesonide/formoterol fumarate - 160/4.5 µg or 320/9.0 µg per inhalation active substances for at least 14 days prior to study enrollment. All study participants will be followed-up for at least 6 months. Data on the efficacy BUFOMIX EASYHALER formulation will be recorded in a Study Questionnaire (SQ) over three consecutive visits (planned according to the rutine clinical needs of the patient), within a period of 6 months from the initiation of the use of BUFOMIX EASYHALER. The efficacy will be assessed on the basis of ACT scale and the results of spirometry and compliance on the basis of the Medication Adherence Questionnaire (MAQ).The role of the study is to establish that new combination therapy budesonide/formoterol fumarate (bufomixeasyhaler 160/4.5 µg or 320/9.0 µg) is efficient and safe in treatment of patients diagnosed with asthma. Non additional diagnostic procedures or monitoring will be used, and all data will be collect during the rutine use of BUFOMIX EASYHALER. Analisis of the collected data will be preformed by epidemiological methods only.

Study status

Finalised

Research institutions and networks

Institutions

Europharma

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Institution

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 08/03/2016

Actual: 08/06/2016

Study start date

Planned: 15/04/2016

Actual: 15/06/2016

Data analysis start date

Planned: 15/12/2016

Actual: 13/12/2016

Date of final study report

Planned: 31/05/2017

Actual: 26/04/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Orion Pharma Poland Sp. z o.o.

Study protocol

ORN-2016-AST PB.pdf(809.41 KB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

the assessment of the efficacy of BUFOMIX EASYHALER® (budesonide/formoterol fumarate 160/4.5 micrograms or 320/9.0 micrograms dose inhalation) in the form of powder for inhalation in patients with asthma.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-Interventional, post-authorization efficacy study

Population studied

Short description of the study population

Adult patients of either sexes with diagnosis of asthma, treated with novel combination therapy of budesonide/formoterol fumarate (BUFOMIX EASYHALER® 160 / 4.5 micrograms or 320 / 9.0 micrograms) at least 14 days before enrollment into the study in Poland by 250 allergist and pulmonologist or doctors currently in course of obtaining these specializations.

Age groups

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

2500

Study design details

Data analysis plan

The Study Questionnaires (SQ) will be transferred from the Study centers to the Office of the Study Organizer will be analyzed in terms of completeness, consistency, clarity and compliance with the Protocol. If data elements are missing from the SQ, the Investigator should state the reason for the missing

data or other deviations from the Protocol. The Office of the Study Organizer will communicate to the Investigator any questions regarding the processing of data and the points that have not been sufficiently explained, for the purpose of clarification or improvement. The Investigator must ensure that all requests for clarification of data are immediately addressed. TheInvestigator is obliged to keep copies of all data, including a record of all changes and clarifications with SQ. Epidemiological and Statistical analysis of the data will be carried out in accordance with the standards of the EU GCP/ICH.

Documents

Study results

Budesonide Publication.pdf(564.68 KB)

Study publications

Pirożyński M, Hantulik P, Almgren-Rachtan A, Chudek J. Evaluation of the effici...

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