ICARUS: Inhaled Corticosteroid And Real life Unlicensed Spacer use – stage 2 (ICARUS 2)

First published: 18/04/2016

Last updated: 02/04/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17815

EU PAS number

EUPAS13194

Study ID

17815

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Examining the real-life unlicensed and licensed use of inhaled corticosteroids with spacers in patients with asthma in the United Kingdom comparing non extra fine beclomethasone in Aerochamber and Volumatic spacers

Study status

Ongoing

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 18/04/2016

Actual: 27/10/2016

Study start date
Planned: 03/01/2017

Actual: 03/01/2017

Data analysis start date
Planned: 04/01/2017

Actual: 04/01/2017

Date of interim report, if expected
Planned: 17/02/2017

Date of final study report
Planned: 24/02/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

chiesi

Study protocol

20161028_R00616_Chiesi_ICARUS2_protocol_v1.3.pdf(1.52 MB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To compare the number of inhaled corticosteroid related adverse events in patients prescribed aerochamber and volumatic spacers and non extra fine beclomethasone

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

BECLOMETASONE PROPIONATE

Medical condition to be studied

Asthma

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

200

Study design details

Outcomes

This is the number of adverse events by questionairre namely reported occurence of oral thrush OR hoarseness, These are database outcomes including evidence of osteoporosis, rash, swelling, glaucoma and adrenal failure in the outcome period

Data analysis plan

The two groups will be compared for the number of adverse events using a Poisson regression model. Non inferiority will be achieved if the proportion of Aerochamber/beclomethasone adverse events (defined by oral thrush or hoarseness) is no more than 13% higher than volumatic/beclomethasone adverse events in the questionnaire returns

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Data sources (types)

Electronic healthcare records (EHR)

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