Inhaled Corticosteroid and Real Life unlicensed Spacer Use (stage 1) (ICARUS 1)

First published: 18/04/2016

Last updated: 02/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS13185

Study ID

13186

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Examining the real-life unlicensed and licensed use of inhaled corticosteroids with or without spacers in patients with asthma in the United Kingdom

Study status

Planned

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

Study start date
Planned: 09/05/2016

Data analysis start date
Planned: 10/05/2016

Date of interim report, if expected
Planned: 06/06/2016

Date of final study report
Planned: 31/08/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

chiesi

Study protocol

20160416_R00616_Chiesi_ICARUS_protocol_stage1_v0.4.pdf (1.63 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:

Drug utilisation

Main study objective:

An exploratory study into the numbers of patients prescribed spacers with non extra fine beclomethasone for asthma in the UK

Study Design

Non-interventional study design

Cross-sectional

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

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- 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

20000

Study design details

Outcomes

Exploratory study into patient numbers using spacers in asthma with non extra fine beclomethasone

Data analysis plan

The number and proportion of patients taking each spacer will be split by demographic characteristics and these will be presented in the final report

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 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