Dose response curves for patients prescribed small & large particle ICS formulation: an observational evaluation of the comparative effect of ICS dose on asthma control achieved in real-life UK patients managed on extrafine hydrofluoroalkane beclomethasone, ciclesonide, fluticasone propionate, or Clenil

First published: 24/07/2015

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Study Finalised

Administrative details

EU PAS number

EUPAS8840

Study ID

27563

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Aims to evaluate the relationship between ICS dose and treatment outcomes for patients prescribed small or large particle formulation by comparing asthma control outcomes associated with different doses of each ICS in order to create real-life dose-response curves.The outcomes evaluated are change in severe exacerbation rates, change in percent predicted PEF and change in average daily SABA dose

Study status

Finalised

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

Actual: 01/02/2013

Study start date

Actual: 01/04/2013

Date of final study report

Actual: 05/11/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva

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

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim of the study was to evaluate the relationship between ICS dose and treatment outcomes for patients prescribed small / large particle formulation by comparing asthma control outcomes and treatment-related side effects associated with different doses of each ICS in order to create real-life dose-response curves.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

FLUTICASONE PROPIONATE

BECLOMETASONE DIPROPIONATE

CICLESONIDE

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Asthma patients prescribed small/large particle formulation of Inhaled corticosteroids (ICS).

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 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

40000

Study design details

Outcomes

Dose-response curves were constructed over the one year outcome period to show patient response to prescribed ICS dose in terms of:• Increase in severe exacerbations• Increase in % predicted peak expiratory flow (PEF)• Increase in average daily SABA use. Characterise the real-life prescribing of each therapy during the outcome period.Characterise the real-life consumption of each

therapy during the outcome period.

Data analysis plan

Dose response curves (“Characteristics of Response” for initiation cohort) were plotted as error bar plots of:• Absolute change in severe exacerbation rate (ATS/ERS defined) from baseline to outcome versus ICS dose prescribed at IPD• Percentage change in severe exacerbation rate (ATS/ERS defined) from baseline to outcome versus ICS dose prescribed at IPD• Change in percent predicted PEF reading from baseline to outcome versus ICS dose prescribed at IPD• Change in average daily SABA use from baseline to outcome versus ICS dose prescribed at IPDThe ICS dose prescribed at IPD was categorised as appropriate for the patient sub-group (i.e. dependent on the frequency and spread of prescribed doses). The ICS dose prescribed may be logged.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data source(s), other

OPCRD United Kingdom

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

Unknown