The use of a spacer in the delivery of large (Fluticasone Propionate) and small particle (Qvar®) inhaled corticosteroid (ICS) in asthma (FP and Qvar Spacer vs Non-Spacer in Asthma)

First published: 23/10/2014

Last updated: 21/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS7744

Study ID

27687

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

The objective of this study is to investigate the real life effectiveness of ICS delivery of Fluticasone Propionate (FP) and Qvar® (beclomethasone dipropionate HFA) by pMDI with spacer compared to pMDI alone.

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: 01/03/2014

Actual: 01/03/2014

Study start date

Planned: 01/04/2014

Actual: 01/04/2014

Date of final study report

Planned: 15/12/2014

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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The objective of this study is to investigate the real life effectiveness of ICS delivery of Fluticasone Propionate (FP) and Qvar® (beclomethasone dipropionate HFA) by pMDI with spacer compared to pMDI alone.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective database study

Study drug and medical condition

Name of medicine, other

Qvar

Anatomical Therapeutic Chemical (ATC) code

(R01AD08) fluticasone

fluticasone

Medical condition to be studied

Asthma

Population studied

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)

Estimated number of subjects

18500

Study design details

Outcomes

ATS exacerbations, Clinical exacerbationsRisk domain asthma controlOverall asthma controlTreatment successSABA useHospitalisationsAdherenceIncidence of oral thrush

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Data analysis plan

Summary statistics will highlight differences in baseline variable distributions between treatment groups. These differences will be quantified using conditional logistic regression models. Treatment arms will be compared using t-test / Mann Whitney U-test (depending on distribution) for variables measured on the interval/ratio scale and using a chi square test for categorical variables.If the exploratory analysis shows significant differences between the cohorts prior to IPD, patients will be matched at IPD for key baseline characteristics, the matching criteria and matching ratio will be determined once the baseline data have been examined. Any residual differences between the treatment arms after matching that are considered to be potentially significant ($p<0.10$) and any variables predictive of the outcome will be adjusted for through further statistical modelling.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data source(s), other

OPCRD United Kingdom

Data sources (types)

Other

Data sources (types), other

This study is a retrospective, effectiveness study consisting of a baseline and outcome period lasting a total of 24 months.This study uses Optimum Patient Care Research Database (OPCRD) which comprises anonymous longitudinal data extracted from approximately 500 UK practices in order to perform reviews of their chronic respiratory services. Data will be supplemented with information from CPRD.

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