Real-life effectiveness evaluation of asthma treatment in Korea

First published: 02/03/2016

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/27681

EU PAS number

EUPAS12279

Study ID

27681

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

Evaluating inhaler device ‘switch success’ and the real-life effectiveness in the Ajou University Hospital Database in Korea

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

David Price

Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/02/2016

Actual: 29/02/2016

Study start date

Planned: 01/04/2016

Actual: 19/08/2016

Data analysis start date

Planned: 29/04/2016

Actual: 01/09/2016

Date of interim report, if expected

Planned: 30/09/2016

Actual: 23/09/2016

Date of final study report

Planned: 01/12/2016

Actual: 27/06/2017

Sources of funding

- Other

- Pharmaceutical company and other private sector

More details on funding

Mundipharma, RIRL

Study protocol

201602013_TransfformAjouv1.pdf(1.45 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 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:

Evaluating inhaler device ‘switch success’ and the real-life effectiveness in the Ajou University Hospital Database in Korea

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

FORMOTEROL FUMARATE

BECLOMETASONE DIPROPIONATE

FLUTICASONE PROPIONATE

FLUTICASONE FUROATE

SALMETEROL XINAFOATE

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Asthma patients that continue to collect prescriptions of new ICS/LABA pMDI after initial prescription.

Patients with following criteria were included:

(1) Codes for asthma (ICD-10) dependent on availability

(2) Aged 12-80 years at date of first prescription for LABA/ICS pMDI or a repeat prescription for LABA/ICS DPI

(3) Active asthma, defined as ≥ 2 prescriptions for LABA/ICS DPI at baseline

(4) ≥ 2 prescriptions for LABA/ICS during outcome period

(5) Same ICS dose at last prescription for LABA/ICS DPI at baseline and first prescription of LABA/ICS after switch date

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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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

400

Study design details

Outcomes

Switch success: Percentage of ICS/LABA pMDI patients who received ≥ 2 prescriptions of ICS/LABA pMDI (i.e. ≥ 1 prescription in addition to that issued at their prescription date) at 6 months and continued on ICS/LABA pMDI, i.e. did not fall back to ICS/LABA DPI. ICS doseTreatment successSABA usageOral steroid prescriptionSevere exacerbation rateRisk domain asthma controlOral thrush incidence

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Data analysis plan

Summary statistics will be produced for all baseline variables. The baseline variables for the two cohorts will be compared using the following tests:• Variables measured on the interval/ratio scale:− t-test (normal distribution)− Mann-Whitney U test (skewed data)• Categorical variables:− Chi-square testResults will be reported as: • Variables measured on the interval/ratio scale:− Sample size (n) and percentage non-missing− Median and inter-quartile range (25th and 75th percentiles)• Categorical variables:− Sample size (n)− Count and percentage by category (distributionIf sufficient numbers are achieved, patients will be matched on baseline variables to assess outcomes between the control (remain on DPI) against comparator (MDI)

Documents

Study results

R01116_Transfform_Ajou_FinalStudyReport_v1.0.pdf(1.74 MB)

Data management

ENCePP Seal

Conflicts of interest of investigators

Conflict of InterestAjou.pdf(92.48 KB)

Composition of steering group and observers

Steering committeeAjou.pdf(92.51 KB)

Data sources

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