Real-life effectiveness evaluation of changing inhaler device for asthma treatment in Korea (Transfform)

First published: 02/03/2016

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/19838

EU PAS number

EUPAS12275

Study ID

19838

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

A historical, observational study to evaluate the real-life effectiveness and cost-effectiveness of asthma treatment in the HIRA Database of Korea specifically examining the switch from the use of dry powder to pressurised metered dose inhalers.

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

Planned: 03/02/2016

Actual: 15/04/2016

Study start date

Planned: 31/03/2016

Actual: 16/09/2016

Data analysis start date

Planned: 29/04/2016

Actual: 23/09/2016

Date of interim report, if expected

Planned: 01/11/2016

Actual: 31/01/2017

Date of final study report

Planned: 02/01/2017

Actual: 11/07/2017

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Mundipharma Asia, RIRL

Study protocol

20160203_TransformHIRAv1.pdf(1.25 MB)

Transfform HIRA Final Study Report_v1.pdf(3.48 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:

To assess asthma outcomes in patients who switch from DPI to pMDI devices and who continue with DPI devices in Korea.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

BUDESONIDE

FORMOTEROL FUMARATE

FLUTICASONE PROPIONATE

FLUTICASONE FUROATE

SALMETEROL XINAFOATE

BECLOMETASONE DIPROPIONATE MONOHYDRATE

BECLOMETASONE DIPROPIONATE

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Asthma patients aged 12-80 years at date of first prescription for LABA/ICS pMDI or a repeat prescription for LABA/ICS DPI obtained from the Korean Health Insurance Review and Assessment (HIRA) service database.

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

2000

Study design details

Outcomes

Switch persistance, defined as: Percentage of ICS/LABA pMDI patients who received ≥ 3 prescriptions of ICS/LABA pMDI in addition to that issued at their prescription date at 6 months, (a) % non-exacerbating patients of ‘switch’ cohort at 1 year, compared to baseline% of ‘switch’ cohort who have no severe exacerbations within 1 year of switching at 1 year, compared to year before switching (b) Severe asthma exacerbation rate (American Thoracic Society/European Respiratory Society statement definition) within the 1 year period

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 (distribution)Based on an expected “switch-back” probability of approximately 0.20 (20%) among patients switching from existing ICS/LABA DPI to ICS/LABA pMDI at their prescription date, a sample size of 100 patients per switch cohort would be sufficient to construct a 95% one-sided confidence interval with an upper bound of less than 0.30 (30%) to power

the evaluation of ICS/LABA pMDI “switch success”

Data management

ENCePP Seal

Conflicts of interest of investigators

transfformHIRAauthoraffiliations.pdf(82.71 KB)

Composition of steering group and observers

steering commiteeHIRA.pdf(94.32 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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