# Real-life effectiveness evaluation of asthma treatment in Korea

First published: 02/03/2016

**Last updated:** 23/04/2024





### Administrative details

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

### **Study status**

Ajou University Hospital Database in Korea

### 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: 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  $\geq$  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

#### **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  $\geq 2$  prescriptions of ICS/LABA pMDI (i.e.  $\geq 1$  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

#### 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**

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.

#### **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