Real-world effectiveness of extra-fine Ciclesonide (Alvesco®) versus standard particle inhaled corticosteroid (ICS)

First published: 24/12/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6147

Study ID

25917

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

Aim of the study:A retrospective, database analysis comparing effectiveness (in terms of exacerbations prevention and asthma control) of Ciclesonide, an extra-fine (EF) particle ICS, with other commonly prescribed standard particle (SP) ICS therapies in patients prescribed asthma therapy from the Netherlands.Data source: the PHARMO Database Network, comprising pharmacy and hospital discharge records for approximately 20% of the Dutch population. Study population: The study population will include patients aged 12-60 years with a history of ≥2 prescriptions for asthma therapy and initiating ICS treatment as EF-ICS ciclesonide or SP-ICS. Data will be collected over one year before (baseline) and one year after (outcome) treatment initiation. Study period is September 2005 – December 2012. Potential COPD patients (>60 years old and those using long-acting muscarinic antagonists) will be excluded.Primary outcomes: Severe exacerbation rate in the year after initiation of ICS therapy, defined as asthma-related hospital admissions OR use of acute oral steroids (based on the American Thoracic Society/European Respiratory Society task force definition).Modified definition of Risk Domain Asthma Control in the year after initiation of ICS therapy, defined as absence of asthma-related hospital admissions AND absence of prescriptions for acute courses of oral steroids.Modified definition of Overall Asthma Control in the year after initiation of ICS therapy defined as no asthma-related hospital admissions AND no prescriptions for acute courses of oral steroids AND average daily dose of ≤200mcg salbutamol / ≤500mcg terbutaline.

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

OPRI Pte Ltd

Multiple centres: 2 centres are involved in the study

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: 31/03/2014

Actual: 18/06/2014

Study start date
Planned: 01/04/2014

Actual: 01/04/2014

Data analysis start date
Planned: 22/05/2014

Actual: 22/05/2014

Date of final study report
Planned: 22/12/2014

Actual: 22/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda Pharmaceuticals

Study protocol

R00114_Ciclesonide Study Protocol_registered_241214.pdf(527.91 KB)

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:

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 compare effectiveness (in terms of asthma control) of extra-fine ICS Ciclesonide (Alvesco) vs standard particle ICS

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Alvesco

Anatomical Therapeutic Chemical (ATC) code

(R01AD) Corticosteroids

Corticosteroids

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Asthma patients aged 12-60 years with a history of ≥2 prescriptions for asthma therapy and initiating inhaled corticosteroid (ICS) treatment as extra-fine (EF)-ICS ciclesonide or standard particle (SP)-ICS who have at least one full year of

baseline data (prior to the prescription date) and at least one full year of outcome data.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

4064

Study design details

Outcomes

(i) Asthma Exacerbation Rate:• Asthma related hospital admissions OR• Use of acute oral steroid .(ii) Risk domain asthma control:• Hospital attendance/admission, AND• Prescriptions for acute courses of oral steroids.(iii) Overall asthma control:• Risk domain asthma control AND• Average daily dose of ≤200mcg salbutamol / ≤500mcg terbutaline, (i) Change in therapy :- Addition of new therapy, including LTRA, THEO or LABA OR, - Patients who increased their ICS therapy by ≥50%.(ii) Average daily short-acting β2-agonists (SABA) usage during outcome year, calculated as average number of puffs per day over the year multiplied by strength.

Data analysis plan

Statistically significant results will be defined as $p<0.05$ and trends as $0.05 \leq p<0.10$Summary statistics will be produced for all baseline and outcome variables, as a complete dataset and by therapy. Treatment groups 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.Outcomes analyses: patients will be matched on demographics and key measures ofdisease severity to ensure comparison of similar patients, using random selection process through SASstatistical software to avoid selection bias.Effectiveness outcomes will be compared between treatment groups using a conditional regression model. The model will use empirical standard errors (for more conservative confidence interval estimations) and adjustments will be made for potential baseline confounders. The adjusted rate ratio with 95% confidence interval will be reported.

Data management

Data sources

Data source(s)

PHARMO Data Network

Data sources (types)

Drug dispensing/prescription data

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