Real-world effectiveness of extrafine vesrus standard particle inhaled corticosteroids: A comparative effectiveness analysis of extrafine (EF) hydrofluoroalkane beclometasone (HFA-BDP) and Ciclesonide versus commonly prescribed standard particle inhaled corticosteroids for patients prescribed asthma therapy in The Netherlands (Extrafine vesrus stand particle ICS effectiveness)

First published: 21/01/2015

Last updated: 21/01/2015

Study Finalised

Administrative details

EU PAS number

EUPAS8391

Study ID

8392

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

Project Description: To compare the effectiveness (in terms of exacerbation prevention and asthma control) of extra-fine vs standard particle ICS in asthma patients initiating or stepping-up ICS therapy in the NetherlandsPatient population: patients receiving asthma therapy other than ICS (adult and paediatric) and initiating ICS therapy as either extra-fine particle ICS (QVAR + Ciclesonide) or standard particle ICS (FP + non-EF-BDP)Data source: Pharmacy and hospital records from the PHARMO Database Network (The Netherlands)

Study status

Finalised

Research institutions and networks

Institutions

Research in Real Life

First published: 01/02/2024

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Institution

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Cristiana Miglio

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2013

Actual: 01/12/2013

Study start date
Planned: 01/12/2013

Actual: 01/12/2013

Data analysis start date
Planned: 01/06/2014

Actual: 01/01/2014

Date of interim report, if expected
Planned: 26/06/2014

Actual: 26/06/2014

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

Teva

Study protocol

R02911_PHARMO main study_study protocol_for registration.pdf(346.15 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim of this study is to compare effectiveness (in terms of asthma control) of EF-ICS and SP-ICS therapies in patients from The Netherlands prescribed asthma therapy .

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03BA) Glucocorticoids

Glucocorticoids

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Patients prescribed asthma therapy in The Netherland who were 5-60 years old. Patients aged 5-60 years who had received ≥ 2 prescriptions for asthma in their records at different points in time at any time AND/OR a diagnostic code for asthma – from hospital records or for patients with linked data from the general practice database, received current inhaled corticosteroids (ICS) therapy (First prescription at ID plus, ≥ 2 ICS prescription during the outcome period (and for increasing cohort only: ≥1 ICSprescription during the baseline period)), and at least one full year of baseline data (prior to the ID) and at least one full year of outcome data(following the ID) were included.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

11181

Study design details

Outcomes

Severe exacerbation:• Asthma-related hospital admissions AND• Prescription for acute courses of oral steroids Risk Domain Asthma Control (RDAC):• Absence of asthma-related hospital admissions OR• Absence of prescription for acute oral steroidsOverall Asthma Control:• Achieved RDAC AND • Average daily dose of ≤200mcg salbutamol / ≤500mcg terbutaline, Treatment stability:• Achieved RDAC• Addition of new therapy, including LTRA, THEO or LABA OR• ICS dose increase by ≥50%• Change ICS type and/or device (sensitivity definition only) Average daily SABA dose prescribed in the year following ICS therapy initiation, calculated as (Count of inhalers * doses per inhalers / 365) * mcg strength

Data analysis plan

Patients will be matched on key baseline characteristics (t-test/chi square test, $p<0.05$). Residual confounders will be adjusted for in the statistical model (multivariate analyses, $p<0.05$). Initial ICS doses (FP-equivalents) will be compared through conditional logistic regression ($p<0.05$). Primary and

secondary outcomes will be compared over the outcome period through conditional logistic regression (CLR) models. Results are expressed as Rate Ratio (RR)/ Odds Ratio (OR) with 95% confidence intervals (CI).

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.

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

No