

# Real-world effectiveness of extrafine versus 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 versus standard particle ICS effectiveness)

**First published:** 21/01/2015

**Last updated:** 21/01/2015

Study

Finalised

## Administrative details

### EU PAS number

EUPAS8391

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### Study ID

8392


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## DARWIN EU® study

No

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### Study countries

 Netherlands

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### 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 Netherlands  
Patient 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)

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### Study status

Finalised

## Research institutions and networks

### Institutions


#### Research in Real Life

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

# The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

 Netherlands

**First published:** 07/01/2022

**Last updated:** 19/12/2025

Institution

Non-Pharmaceutical company

ENCePP partner

## Contact details

### Study institution contact

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Study 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

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**Study start date**

Planned: 01/12/2013

Actual: 01/12/2013

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**Data analysis start date**

Planned: 01/06/2014

Actual: 01/01/2014

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**Date of interim report, if expected**

Planned: 26/06/2014

Actual: 26/06/2014

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

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### **Medical condition to be studied**

Asthma

## Population studied

### **Short description of the study population**

Patients prescribed asthma therapy in The Netherlands who were 5-60 years old. Patients aged 5-60 years who had received  $\geq 2$  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,  $\geq 2$  ICS prescription during the outcome period (and for increasing cohort only:  $\geq 1$  ICS prescription 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.

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### **Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

- Adults (46 to < 65 years)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Asthma patients

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### **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 steroids  
Overall Asthma Control: • Achieved RDAC AND • Average daily dose of  $\leq 200$ mcg salbutamol /  $\leq 500$ mcg terbutaline, Treatment stability: • Achieved RDAC • Addition of new therapy, including LTRA, THEO or LABA OR • ICS dose increase by  $\geq 50\%$  • 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

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### **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

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### Data sources (types)

[Drug dispensing/prescription data](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No