

Dose response curves for patients prescribed small & large particle ICS formulation: an observational evaluation of the comparative effect of ICS dose on asthma control achieved in real-life UK patients managed on extrafine hydrofluoroalkane beclomethasone, ciclesonide, fluticasone propionate, or Clenil

**First published:** 24/07/2015

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Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/27563>

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### **EU PAS number**

EUPAS8840

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**Study ID**27563

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**DARWIN EU® study**No

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**Study countries** United Kingdom

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**Study description**

Aims to evaluate the relationship between ICS dose and treatment outcomes for patients prescribed small or large particle formulation by comparing asthma control outcomes associated with different doses of each ICS in order to create real-life dose-response curves. The outcomes evaluated are change in severe exacerbation rates, change in percent predicted PEF and change in average daily SABA dose

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**Study status**

Finalised

## Research institutions and networks

### Institutions

[Observational & Pragmatic Research Institute Pte \(OPRI\)](#)

 United Kingdom**First published:** 06/10/2015

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**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**ENCePP partner**

## Contact details

### Study institution contact

David Price

**Study contact**

[dprice@opri.sg](mailto:dprice@opri.sg)

### Primary lead investigator

David Price

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 01/02/2013

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### Study start date

Actual: 01/04/2013

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### Date of final study report

Actual: 05/11/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Teva

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **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

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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 the study was to evaluate the relationship between ICS dose and treatment outcomes for patients prescribed small / large particle formulation by comparing asthma control outcomes and treatment-related side effects associated with different doses of each ICS in order to create real-life dose-response curves.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

FLUTICASONE PROPIONATE

BECLOMETASONE DIPROPIONATE

CICLESONIDE

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**Medical condition to be studied**

Asthma

## Population studied

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

Asthma patients prescribed small/large particle formulation of Inhaled corticosteroids (ICS).

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### **Age groups**

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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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**

40000

## **Study design details**

### **Outcomes**

Dose-response curves were constructed over the one year outcome period to show patient response to prescribed ICS dose in terms of:

- Increase in severe exacerbations
- Increase in % predicted peak expiratory flow (PEF)
- Increase in average daily SABA use.

Characterise the real-life prescribing of each therapy during the outcome period. Characterise the real-life consumption of each

therapy during the outcome period.

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### **Data analysis plan**

Dose response curves (“Characteristics of Response” for initiation cohort) were plotted as error bar plots of:

- Absolute change in severe exacerbation rate (ATS/ERS defined) from baseline to outcome versus ICS dose prescribed at IPD
- Percentage change in severe exacerbation rate (ATS/ERS defined) from baseline to outcome versus ICS dose prescribed at IPD
- Change in percent predicted PEF reading from baseline to outcome versus ICS dose prescribed at IPD
- Change in average daily SABA use from baseline to outcome versus ICS dose prescribed at IPD

The ICS dose prescribed at IPD was categorised as appropriate for the patient sub-group (i.e. dependent on the frequency and spread of prescribed doses). The ICS dose prescribed may be logged.

## Data management

### Data sources

#### **Data source(s)**

Clinical Practice Research Datalink

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#### **Data source(s), other**

OPCRD United Kingdom

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#### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

### 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**

Unknown