

An observational cohort study to describe intermittent OCS utilisation and its association with adverse outcomes and healthcare resource use and costs in asthma using the OPCR and CPRD databases. (The burden of intermittent OCS use in asthma)

**First published:** 04/09/2020

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS37065

### Study ID

47879

### DARWIN EU® study

No

## Study countries

☐ United Kingdom

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## Study description

Background/Rationale: Oral corticosteroids (OCS) are frequently prescribed for patients with respiratory conditions such as asthma. Despite evidence on the adverse outcomes of OCS, their use remains part of the clinical guidelines for asthma. There is evidence showing that relatively low cumulative doses of OCS can increase the risk of adverse outcomes and there is a wide consensus among physicians and researchers that the use of OCS should be limited to a minimum and should only be used when no other treatment option is available. Despite this OCS are still widely prescribed for patients with mild asthma. Whilst there is evidence showing increased risk of adverse events related to cumulative OCS dose there is little showing how patterns of intermittent OCS use are related to adverse events and related healthcare costs. Objectives: 1. To classify intermittent OCS prescriptions for patients with asthma and to describe longitudinal patterns of intermittent (acute) OCS use by Global Initiative for Asthma (GINA) step, and Inhaled Corticosteroids (ICS) and Short-Acting Beta-Agonists (SABA) use. 2. To assess the association between differing patterns of intermittent OCS use and OCS-related adverse events (AE) in patients with asthma 3. To describe the impact of different patterns of intermittent OCS use on the frequency of healthcare resource utilisation (HRU) in patients with asthma. 4. To describe the AE for patients with an average annual OCS dose of 250-499mg, 500-999mg, or  $\geq 1$ g of OCS during the follow up.

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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

**Last updated:** 19/08/2024

**Institution**

Educational Institution

Laboratory/Research/Testing facility

ENCePP partner

### 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

### Clinical Practice Research Datalink (CPRD)

☐ United Kingdom

**First published:** 15/03/2010

**Last updated:** 17/01/2025

**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

Actual: 16/12/2019

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### Study start date

Planned: 07/09/2020

Actual: 07/09/2020

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### Data analysis start date

Planned: 05/10/2020

Actual: 05/10/2020

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**Date of interim report, if expected**

Planned: 29/01/2021

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**Date of final study report**

Planned: 05/04/2021

Actual: 31/08/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Astra Zeneca

## Study protocol

[Intermittent OCS Protocol v6.3.pdf](#)(1.06 MB)

[Intermittent OCS Protocol v6.5 JC 20220128.docx.pdf](#)(1.03 MB)

## 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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Healthcare resource utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

1 To classify intermittent OCS prescriptions asthma patients and to describe by SABA and ICS use 2 To assess the association between patterns of intermittent OCS use and OCS-related adverse outcomes in patients with asthma. 3 To describe the impact of patterns of intermittent OCS use on the frequency of healthcare resource utilisation 4 To describe AEs for patients different average OCS doses

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Historical longitudinal descriptive study

## Study drug and medical condition

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

Asthma

Type 2 diabetes mellitus

Osteoporosis

Osteoporotic fracture

Hypertension

Glaucoma

Sleep apnoea syndrome

Weight increased

Depression

Anxiety

Pneumonia

Cataract

Chronic kidney disease

Dyslipidaemia

Peptic ulcer

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### **Additional medical condition(s)**

Sleep disorders, Cardiovascular disease, Growth suppression and behavioural disorders

## **Population studied**

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

The study population included patients aged 4 years or older received oral corticosteroids (OCS) for the treatment of asthma identified from the optimum patient care research database (OPCRD) and clinical practice research datalink (CPRD).

#### Inclusion Criteria:

1. OCS Arm - Patients with a prescription of an OCS with a concurrent (within 3 months) asthma event defined as an asthma QOF diagnosis or asthma QOF prescription. This will be the index date.
2. Non-OCS Arm - Patients with no OCS prescription at any time
3. Patients with at least 12 months baseline period (prior to index date)
4. Patients aged 4 or over at the index date

#### Exclusion Criteria:

1. Patients with a diagnosis, ever, for a chronic condition treated with OCS
  2. Patients with a chronic AE outcome prior to the index date will be excluded from the analysis. This will ensure that the first chronic condition is the post index date incident event.
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#### **Age groups**

Children (2 to < 12 years)

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)

Adults (85 years and over)

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#### **Special population of interest**

Other

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

Patients with asthma

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## **Estimated number of subjects**

1200000

## **Study design details**

### **Outcomes**

Primary outcome will be a diagnosis of type 2 diabetes mellitus, osteoporosis/osteoporotic fractures, hypertension, glaucoma, sleep apnoea, weight gain and depression/anxiety, pneumonia, cataracts, sleep disorders, cardiovascular disease, chronic kidney disease, dyslipidaemia and peptic ulcer disease, and in the adolescent population we will look for growth suppression and behavioural disorders, Healthcare resource utilisation

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### **Data analysis plan**

Objective 1: Baseline characteristics will be described for patients according to their longitudinal patterns of intermittent OCS use by GINA step, and ICS and SABA use. Objective 2: A matched historical cohort study will be performed with an assessment of potential confounders during a baseline period prior to the index date. Patients will be excluded if they had a record of the adverse event prior to their index date and categorised according to their patterns of OCS prescribing. Patients will be matched initially on gender, age, and the index date. Other potential confounders will be identified during the analysis, using potential bias assessments of covariates. Objective 3: HRU events will be described over the follow up period using the CPRD dataset. HRU events will be described in the baseline period and during the follow up for asthma-related and all-cause events using linked CPRD & HES. Objective 4: Describe the AE for patients with an average annual OCS doses.

## **Documents**

## Study results

[Intermittent OCS Report v4.1 - clean.pdf\(7.83 MB\)](#)

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## Study publications

[Haughney J, Tran TN, Heatley H, Bourdin A, Menzies-Gow A, Jackson DJ, Maslova E...](#)

[Heatley H, Tran TN, Bourdin A, et al. Observational UK cohort study to describe...](#)

[Heatley H., Tran T., Bourdin A., Menzies-Gow A., Jackson D., Maslova E., Skinne...](#)

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## Data management

### Data sources

#### Data source(s)

Clinical Practice Research Datalink

Optimum Patient Care Research Database

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#### Data source(s), other

CPRD, Optimum Patient Care Research Database (OPCRD)

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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**

No