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 OPCRD 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

PURI

https://redirect.ema.europa.eu/resource/47879

EU PAS number

EUPAS37065

Study ID

47879

DARWIN EU® study

No

Study countries

☐ United Kingdom

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 =>1g of OCS during the follow up.

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

Study start date

Planned: 07/09/2020

Actual: 07/09/2020

Data analysis start date

Planned: 05/10/2020

Actual: 05/10/2020

Date of interim report, if expected
Planned: 29/01/2021

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

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Healthcare resource utilisation

Data collection methods:

Secondary use of data

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

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

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.

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)

Special population of interest

Other

Special population of interest, other

Patients with asthma

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)

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...

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Optimum Patient Care Research Database

Data source(s), other

CPRD, Optimum Patient Care Research Database (OPCRD)

Data sources (types)

Electronic healthcare records (EHR)

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