

Longitudinal systemic corticosteroid utilization in the UK, 1990-2018

First published: 03/09/2019

Last updated: 21/02/2024

Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/31699>

EU PAS number

EUPAS30943

Study ID

31699

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The study is a historical longitudinal descriptive cohort study, describing the systemic corticosteroid use in patients with a condition (28 initially selected) for which SCS are used between 1990 and 2018. For each of the selected conditions, for each calendar year the number of patients with active condition will be collected, and for these the number of prescriptions for systemic corticosteroids and the total dose taken will be collected. With these data changes in SCS utilisation after the introduction of new SCS-sparing therapies and/or relevant guideline changes will be described.

Study status

Ongoing

Research institution and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated

23/11/2016

Institution

Educational Institution

Laboratory/Research/Testing facility

ENCePP partner

Contact details

Study institution contact

David Price

Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual:

03/06/2019

Study start date

Planned:

02/09/2019

Actual:

02/09/2019

Data analysis start date

Planned:

03/09/2019

Actual:

03/09/2019

Date of interim report, if expected

Planned:

15/12/2019

Date of final study report

Planned:

01/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

[OPRI_1855_Protocol_190813.pdf](#)(1.14 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 type:

Scope of the study:

Drug utilisation

Main study objective:

To describe systemic corticosteroid use over time in up to 28 conditions, including asthma and COPD. To describe changes around the introduction of SCS-sparing therapies (e.g. biologics) and/or relevant treatment guideline changes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H02B) CORTICOSTEROIDS FOR SYSTEMIC USE, COMBINATIONS

Population studied

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)

Estimated number of subjects

6000000

Study design details

Data analysis plan

The study is a historical longitudinal descriptive cohort study, describing the systemic corticosteroid use in patients with a condition (28 initially selected) for which SCS are used between 1990 and 2018. For each of the selected conditions, for each calendar year the number of patients with active condition will be collected, and for these the number of prescriptions for systemic corticosteroids and the total dose taken will be collected. With

these data changes in SCS utilisation after the introduction of new SCS-sparing therapies and/or relevant guideline changes will be described.

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Data source(s), other

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