An observational historical cohort study to evaluate chronic disease onset associated with long-term oral corticosteroid and it’s cost impact on patients in the OPCRD / CPRD databases

First published: 08/12/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15175

Study ID

27222

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A matched historical cohort study to determine side effects of long-term/intermittent use of oral corticosteroids (OCS) and to measure the mean time required for the onset of side effects in patients prescribed OCS.

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

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

Planned: 06/09/2016

Actual: 06/09/2016

Study start date

Planned: 01/11/2016

Actual: 25/11/2016

Data analysis start date

Planned: 20/12/2016

Date of interim report, if expected

Planned: 31/01/2017

Date of final study report

Planned: 29/09/2017

Actual: 31/07/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To establish the association between long term (total dose, total duration and average total daily dose and current measures (current dose and current use) of OCS exposure and incidence of related conditions such as type 2 diabetes mellitus, osteoporosis/ osteoporotic fractures, hypertension, glaucoma, sleep apnoea, weight gain and depression/anxiety.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Historical cohort database study

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Hypertension

Osteoporosis

Sleep disorder

Sleep apnoea syndrome

Pneumonia

Glaucoma

Cataract

Depression

Anxiety

Population studied

Short description of the study population

Patients in OPCRD / CPRD databases prescribed with long-term oral corticosteroid

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Age groups

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

108217

Study design details

Outcomes

type 2 diabetes, 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.Annualised healthcare resource utilisation and related cost

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Data analysis plan

Different time-dependent OCS exposure measures will be explored, defined as current use (yes/no), current dose (mg/day), total dose (g), total duration of exposure (months) and average total daily dose (mg/day). For each corticosteroid related condition, multivariable Cox proportional hazard models will be fitted separately for each of the five time-dependent OCS exposure measures. To determine critical OCS dose thresholds, total dose and daily dose will be categorised into relevant levels and the risk of developing the outcome of interest will be compared between each category of corticosteroid treatment arm and control arm.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

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

Unknown