Metabolic effects associated with ICS (inhaled corticosteroid) use in COPD (chronic obstructive pulmonary disease) patients with type II diabetes

First published: 20/06/2014
Last updated: 15/05/2015

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/9743

EU PAS number
EUPAS6804

Study ID
9743

DARWIN EU® study
No

Study countries
United Kingdom

Study description
Lay Summary: Current international guidelines for the management of chronic obstructive pulmonary disease (COPD, GOLD 2014) recommend inhaled corticosteroids (ICS) are reserved for COPD patients with severe/very severe disease and/or frequent exacerbations. However, research shows widespread use of ICS in patients with mild and moderate disease, meaning more patients are exposed to risks of side effects than would be expected under current guidelines. High doses of ICS as those typically prescribed to COPD patients have been linked to increased risks of diabetes onset and progression, yet no study has investigated this association in a cohort of COPD patients in the UK. The

proposed study will investigate whether ICS treatment in COPD patients with comorbid type II diabetes has a negative impact on diabetic control, and determine whether COPD patients treated with ICS outside of guidelines are at unnecessary risk of diabetes progression. The intended audience for this study is prescribers. We plan to publish the results of this study initially at a conference, then as a manuscript in a peer-reviewed journal.

Study status
Finalised

Research institution and networks

Institutions

Research in Real Life
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Institution

Contact details

Study institution contact
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Study contact

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Study timelines

Date when funding contract was signed
Actual:
04/06/2014

Study start date
Planned:
01/07/2014

Actual:
01/08/2014

Data analysis start date
Planned:
21/07/2014
Actual:
11/08/2014

Date of interim report, if expected
Planned:
31/08/2014
Actual:
07/11/2014

Date of final study report
Planned:
15/04/2015
Actual:
15/04/2015

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Boehringer Ingelheim, RiRL

Study protocol

ENCePP protocol submission - ICS-diabetes-COPD.pdf(316.08 KB)

Regulatory

Was the study required by a regulatory body?
No

Methodological aspects

Study type

Study type list

Study topic:
Human medicinal product
Disease /health condition

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:
Secondary data collection

Main study objective:
To assess whether ICS use (within and outside of GOLD guidelines) is associated with an increase in glycated haemoglobin (HbA1c) value (%) in COPD patients with type II diabetes.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(R03B) OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

Medical condition to be studied
Type 2 diabetes mellitus
Chronic obstructive pulmonary disease

Population studied

Short description of the study population
COPD patients with comorbid type II diabetes aged ? 40 years at index date.

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)

Special population of interest
Other

Special population of interest, other
Chronic obstructive pulmonary disease (COPD) patients with comorbid diabetes mellitus

Estimated number of subjects
1088

Study design details

Outcomes
Change in HbA1c value (%) relative to baseline. (a) Change in HbA1c with a change in anti-diabetic medication - (b) Change in number of patients on/off HbA1c target (< 7.5% as per UK QOF indicators) with no change in anti-diabetic medication - (c) No change in HbA1c with an increase in GP visits, hospital visits and glucose strip use - (d) Progression of ongoing diabetes treatment to insulin

Data analysis plan
This will be a retrospective cohort study with a one year outcome period after an index prescription date. The index prescription date refers to either the first prescription of ICS (ICS-initiating cohort) or the first prescription of LABA or LAMA (no ICS therapy cohort). Patients in the ICS-initiating cohort will be matched to patients in the no ICS therapy cohort (i.e. control cohort), using a set of baseline characteristics. For the primary outcome, mean one-year change in HbA1c value (%) will be compared across the two study cohorts. Internal validity will be addressed by matching patients on baseline characteristics and controlling for potential confounders during statistical analyses. External validity will be achieved by using large primary care databases, which have been shown to be generalizable to the UK population.

Data management

Data sources

Data source(s)
Clinical Practice Research Datalink

Data source(s), other
Optimum Patient Care Research Database (OPCRD) United Kingdom

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