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

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 institutions and networks

Institutions

Research in Real Life

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Institution

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

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 use of data

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

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

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Estimated number of subjects

1.088

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

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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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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