Implications of ICS withdrawal in the real-life management of COPD

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/41925

EU PAS number

EUPAS30851

Study ID

41925

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This will be a retrospective study using electronic medical records and linked COPD questionnaire data from the Optimum Patient Care Research Database (OPCRD). The sutdy will evaluate the effect of ICS cessation in patients with confirmed COPD, managed in a primary care, “real-life” setting. Specifically, it will compare the exacerbation rates and lung function of patients who stop ICS therapy to those who continue on triple therapy.

Study status

Finalised

Research institutions and networks

Networks

Respiratory Effectiveness Group (REG)

- ☐ Belgium
- ☐ Denmark
- ☐ France
- ☐ Germany
- ☐ Greece
- ☐ Hungary
- ☐ Italy
- ☐ Netherlands
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom

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Network | ENCePP partner

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

Planned: 30/08/2019

Actual: 03/09/2019

Study start date

Planned: 02/09/2019

Actual: 10/09/2019

Data analysis start date

Planned: 01/10/2019

Actual: 02/12/2019

Date of final study report

Planned: 13/01/2020

Actual: 26/10/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Evaluate the effect of ICS cessation in patients with confirmed COPD, managed in a primary care, “real-life” setting. Specifically investigating the effects of ICS withdrawal on - 1) Exacerbation rates 2) Lung function

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational comparative effectiveness study

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Chronic obstructive pulmonary disease patients.
Patients were required to have ≥ 2 fixed dose ICS/LABA and separate LAMA prescriptions, or ≥ 2 fixed dose ICS/LABA/LAMA prescriptions, in the baseline year. The IPD for the cessation group was the first prescription for a single LABA alongside a single LAMA, or a fixed dose LABA/LAMA, without ICS.

The control group patients were required to have ≥ 1 fixed or free combination of ICS/LABA/LAMA in the outcome year. Their index prescription date (IPD) was the date when the patient received a repeated prescription for their baseline triple therapy.
Patients were required to have an IPD prior to 1/12/2018 to allow for a 1-year outcome period; in patients with more than one IPD the first IPD was used for analysis.
Inclusion criteria were: (A) spirometry-confirmed diagnosis of COPD (Read code and FEV1/FVC < 0.7 within 2 years, ever recorded); (B) aged ≥ 40 years at IPD; (C) current or ex-smoker; (D) have ≥ 1 year of continuous patient records in prior to IPD; and (E) ICS medication possession ratio (MPR, (Number of days supplied in period/Days in period) × 100) ≥ 70% in the baseline year.

Exclusion criteria were: (A) asthma Read code during the baseline year; (B) prescribed azithromycin or roflumilast or receiving maintenance treatment with systemic steroids. Patients were excluded from the control group if they had

ever had an ICS cessation prior to IPD.

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

Estimated number of subjects

3000

Study design details

Outcomes

Time to COPD exacerbation, Exacerbation rate/ Change in FEV1/ Time to addition or change in therapy/ ICS containing treatment adherence/ CAT score/ MRC Dyspnea scale/ Time to last record in database where there is a lack of continuous records (proxy for mortality)/ Time to first consultation with a pneumonia Read code

Data analysis plan

Assuming that the rate of drop out from the database/mortality rate (where recorded) are not significantly different between the ICS cessation and control

arm then only those patients with ≥ 1 year of continuous database records post IPD date will be included in the multivariate regression analyses. We will use an intention to treat analysis. Multivariate regression analyses will be used to adjust for confounding variables. Primary outcome - time to event will be analysed using conditional cox proportional hazards regression. Secondary outcomes- will be analysed with conditional logistic, poisson or cox regression, as appropriate.

Documents

Study publications

Magnussen H, Lucas S, Lapperre T, Quint JK, Dandurand RJ, Roche N, Papi A, Pric…

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