Benefits of high dose ICS in patients with asthma and high blood eosinophil counts

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/15870

EU PAS number

EUPAS15869

Study ID

15870

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A previous study conducted by the Observational and Pragmatic Research Institute (OPRI) found that patients with asthma and high blood eosinophil counts experience more severe exacerbations and have poorer asthma control. The results suggest that this subpopulation of patients with asthma does not respond well to guideline-recommended therapy.There is no evidence available that a step-up to high dose ICS would be effective in preventing asthma attacks in these patients.Nevertheless, high ICS doses are frequently prescribed in real-life, exposing patients to the risk of adverse effects. The objective is to study the effectiveness of initiating patients with high blood eosinophil counts on high dose ICS to reduce exacerbation risk and to achieve asthma control.Patients with asthma and high blood eosinophil counts who step-up to high dose ICS will be extracted from the Clinical Practice Research Datalink or the Optimum Patient Care Research Database (date is index date (ID)).Patients who step-up from medium to high dose ICS will be matched to and compared with control patients on stable medium dose treatment during follow-up. The ID of control patients will be chosen at exactly the same number of days after the date of blood eosinophil count recording as the matched step-up patient.Patients who step up from low to high dose ICS will be matched to and compared with patients who step up from low to medium dose ICS.Patients will be matched on the following characteristics assessed in the year prior to ID: timing and value of eosinophil count, number of exacerbations, ICS drug and dose, propensity score of high dose ICS assignment.Survival and negative binomial regression analyses will be used to compare the rates of asthma exacerbations over 1 and 3 years of follow-up.

Study status

Planned

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

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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

Planned: 30/05/2016

Actual: 30/05/2016

Study start date
Planned: 09/09/2016

Data analysis start date
Planned: 17/10/2016

Date of interim report, if expected
Planned: 03/02/2017

Date of final study report
Planned: 31/03/2017

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:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To study the effectiveness of initiating patients with high blood eosinophil counts on high ICS doses to reduce future exacerbation risk and to achieve asthma cont

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Age groups

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

7200

Study design details

Outcomes

Number of severe asthma exacerbations, Acute oral corticosteroid courses for respiratory conditionsHospitalizations for asthma exacerbationAcute respiratory eventsExcessive use of Short-acting ß2-agonists (SABA)

Data analysis plan

Conditional Cox regression will be performed with time to the first event during stable ICS treatment as the outcome variable to estimate HRs with 95% CI. Right censoring will be applied when a change in ICS prescriptions is observed during follow up.Conditional negative binomial regression / logistic regression with the number of events per time periods of one and three years will be performed to estimate RRs / ORs with 95% CI for patients with a continuous follow up time without a change in ICS prescription for these time periods.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Optimum Patient Care Research Database

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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