The role of adherence to inhaled corticosteroids in the relationship between blood eosinophilia and asthma control

First published: 03/11/2015

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26263

EU PAS number

EUPAS11512

Study ID

26263

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Patients with asthma and >0.4x109 blood eosinophils/L are characterized by increased severe exacerbation rates, reduced odds of achieving asthma control and being at higher steps of the GINA guidelines (step 3-4), compared to patients with asthma and lower eosinophil counts (<0.4x109/L).Alternative therapies that target raised eosinophil counts are being introduced to the market but there is some concern that these treatments will only work for patients with poor adherence to their asthma therapy.A recent RiRL study found that within the UK, a high proportion of patients at higher GINA steps appear to be adherent to therapy but remain uncontrolled in terms of exacerbations and symptoms. Therefore, there is a need to clarify whether there exists a population of patients with asthma who have persistent elevated blood eosinophil counts, persistent exacerbations and who are adherent to ICS.

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

Bakhtiyor Khalikulov

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/03/2015

Study start date

Actual: 30/03/2015

Date of final study report

Planned: 30/12/2015

Actual: 30/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva

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:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To investigate whether poor adherence to ICS therapy explains occurrence of exacerbations or poor asthma control in patients with raised blood eosinophil counts at steps 3 and 4 of the GINA guidelines.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Asthma patients with raised blood eosinophil counts at steps 3 and 4 of the GINA guidelines.

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

Asthma patients

Estimated number of subjects

7195

Study design details

Outcomes

Demographic and clinical characteristics of the patients with raised and normal eosinophil levels at steps 3 or 4 of the GINA guidelines. Patterns of adherence to the ICS treatment in the asthma patients with raised and normal blood eosinophil levels at steps 3 and 4 of the GINA guidelines

Data analysis plan

Descriptive statistics of the demographic and clinical characteristics of the patients with raised and normal eosinophil levels at steps 3 or 4 of the GINA guidelines will be produced. The number (%) of patients with exacerbations (routine, patient-reported and combined variables) and the proportion of patients with controlled asthma (routine and patient-reported variables) will be calculated. Sensitivity analyses for patients with good treatment adherence (>80%), as well as for lower adherence levels (≤80%) using eosinophils

recordings within one year from questionnaire collection and lower cut-off for eosinophil levels (>0.3 x 109/L and ≤0.3 x 109/L) will be performed.Statistically significant results will be defined as $p < 0.05$ and trends as $0.05 \leq p < 0.10$. Differences between groups will be evaluated through Chi-square or Mann-Whitney U tests, as appropriate. Intra-group differences will be evaluated through Chi-square test ($p<0.05$).

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Data source(s), other

iHARP 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

Unknown