Targeting therapy in people with severe asthma: A retrospective cohort study describing commonly measured biomarkers (eosinophil count and IgE levels) in patients with severe asthma

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Study Finalised

Administrative details

EU PAS number

EUPAS13134

Study ID

26694

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

With the introduction of novel therapies for asthma, it will be useful to differentiate patient need by clinical status (severity) and biomarkers.Patients with severe asthma may be eligible for these potentially life transforming treatments. Biological therapies demonstrate successful outcomes but are (and as new therapies become available, will be) restricted in use by both an assessment of need after optimised care and a biomarker profile consistent with product licenses. Two biomarkers of interest are currently available in routine clinical practice, Blood eosinophil count and total and specific IgE levels. The biological therapy omalizumab may be indicated in patients with severe asthma and an appropriate, raised, IgE. Anti Il-5s (and other therapies) may be indicated in patients with severe asthma and raised blood eosinophil counts. As periostin estimation is not currently in routine use, this biomarker (and its possible guide to Il-13 drug therapy) is not considered in this project.One traditional view is that eosinophil counts and IgE levels are associated. Recent anecdotal evidence proposes that the relationship may not be consistent and that a group of patients who are both eosinophil high and IgE low may exist, for example.By defining the biomarker status of a cohort of people with severe asthma we can estimate the potential impact of precision medicine through appropriate biological therapies for these patients.A preliminary search of the NHS Greater Glasgow and Clyde (NHSGGC) Safe Haven database (n=1.4 million) revealed that about 10,000 IgE levels were requested last year Of these, 1850 were from patients aged 18 years or over who had a Read or ICD code for asthma Study aim: To categorise people with severe asthma according to their eosinophil and total IgE biomarker status.

Study status

Finalised

Research institutions and networks

Institutions

NHSGGC

Contact details

Study institution contact

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Study contact

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Primary lead investigator

John Haughney

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/03/2016

Actual: 08/03/2016

Study start date

Planned: 18/04/2016

Actual: 02/05/2016

Data analysis start date

Planned: 02/05/2016

Actual: 16/05/2016

Date of interim report, if expected

Planned: 16/05/2016

Actual: 16/05/2016

Date of final study report

Planned: 16/05/2016

Actual: 27/07/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva UK

Study protocol

Eosinophil in severe asthma study FINAL_ Feb 2016.pdf (124.8 KB)

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To categorise people with severe asthma according to their eosinophil and total IgE biomarker status.

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

All patients currently on the NHSGGC database who had read or ICD coded diagnosis for asthma ever recorded, age ≥ 18 years two years prior to the index date, ≥ 1 prescription for any of SABA, ICS, ICS/LABA combination in the two years prior to the index date, ≥ 1 estimation of IgE in the two years prior to the 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

Asthma patients

Estimated number of subjects

2000

Study design details

Outcomes

Description and correlation coefficient of maximum EOS versus maximum IgE among those with asthma and receiving therapy at British Thoracic Society step

4 level and above, Number with same day biomarker measurementMaximum IgE in past 2 years Maximum EOS in past 2 years Same day EOS versus same day IgE. Maximum EOS by compliance with inhaled steroid medication Characteristics of patients at BTS step 4 and above by EOS/IgE combination group Number fulfilling the criteria for Xolair and the possible criteria for reslizumab Truncated

Data analysis plan

Creation of new IgE and EOS variables− Maximum IgE in past two years − An IgE >75 and ≤1500 at any time in past two years − The number of measurements of IgE levels in past two years − The value of IgE corresponding to the same day measurement as EOS at any time in past two years − Maximum EOS in past two years − An EOS ≥400 at any time in the past two years − The number of measurements and the proportion of EOS levels ≥400 in the past two years − The value of EOS corresponding to the same day measurement as IgE at any time in the past two years Frequency plots to illustrate the distribution of the continuous variables. Scatterplots to assess the relationship between two continuous variables such as IgE and EOS. Correlation coefficients to assess the linear relationship between two continuous variables such as IgE and EOS (Spearmans correlation will be used if both variables are skewed and Pearson correlation if one or both variables are normally distributed).

Documents

Study results

1-s2.0-S0954611117304146-main.pdf (455.7 KB)

Study publications

Haughney J, Morice A, Blyth KG, Lee AJ, Coutts A, McKnight E, Pavord I. A retro...

Data management

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 sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Drug registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

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