Burden of severe uncontrolled eosinophilic asthma in the UK population

First published: 03/09/2015

Last updated: 22/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS10229

Study ID

12824

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Background/Rationale:Benralizumab is a monoclonal antibody against the Interleukine-5 receptor, currently undergoing phase 3 clinical trials for use in the treatment of asthma. This therapy is being developed by AstraZeneca.

Benralizumab will target patients with severe, uncontrolled eosinophilic asthma treated with the combination of a high dose of inhaled corticosteroids (ICS) with a long-acting beta2-agonist (LABA).There is a need to establish the proportion of patients with severe uncontrolled eosinophilic asthma among the total population of asthma patients who would be eligible to be treated with benralizumab and to describe their burden of illness and healthcare resource utilisation (HRU).Objectives:The first objective is to describe the distribution of asthma severity, control, treatment status and blood eosinophilia and to establish the proportion of patients with severe uncontrolled eosinophilic asthma among the total population of asthma patients.The second objective will be to assess the rate of exacerbations and HRU during a follow-up year among patients with severe uncontrolled eosinophilic asthma.Study design: Patients with active asthma will be selected from the Clinical Practice Research Datalink (CPRD) and the Optimum Patient Care Research Database (OPCRD).The distribution of asthma severity and control, treatment status, blood eosinophilia, other asthma determinants and their combinations will be described in a baseline year prior to the date of the last blood eosinophil count (index date). Analyses will be performed in patients with and without an overlapping diagnosis of COPD separately.The rate of exacerbations and HRU will be described in the year after the index date in patients with severe uncontrolled eosinophilic asthma, defined as patients with blood eosinophilia, treated with high-dose ICS+LABA, who had ≥2 exacerbations for asthma in the baseline year.

Study status

Ongoing

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

Kerkhof Marjan marjan@rirl.org

Study contact

marjan@rirl.org

Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/01/2014

Actual: 06/03/2015

Study start date
Planned: 06/07/2015

Actual: 27/07/2015

Data analysis start date
Planned: 26/08/2015

Actual: 15/10/2015

Date of interim report, if expected
Planned: 25/09/2015

Actual: 11/02/2016

Date of final study report
Planned: 15/04/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

Study protocol burden of severe uncontrolled eosinophilic asthma Final 26082015.pdf(680.93 KB)

20160304 Study protocol burden of severe uncontrolled eosinophilic asthma.pdf (798.41 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

The main objective is to describe the size of the population of patients with severe uncontrolled eosinophilic asthma and their burden of disease and health care resource utilisation

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Age groups

Children (2 to < 12 years)

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

200000

Study design details

Outcomes

Asthma exacerbations and Healthcare Resource Utilisation, Indirect costs of asthma exacerbations

---

Data analysis plan

A historical follow-up study will be performed among the UK population of patients with active asthma extracted from OPCRD and CPRD at the last recorded blood eosinophil count (index date).The distribution of asthma severity and control, treatment status, blood eosinophilia, other asthma determinants and their combinations will be described in the baseline year prior to the index

date in the total population and stratified by four age groups and the presence of blood eosinophilia using three cut-off values. The rate of exacerbations and HRU will be described in the outcome year in patients with severe uncontrolled eosinophilic asthma, defined as patients with blood eosinophilia, treated with high dose ICS + LABA who had ≥2 exacerbations in the baseline year. All analyses are performed in patients with and without an overlapping diagnosis of COPD separately.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data source(s), other

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