The healthcare costs associated with comorbidities of refractory asthma and systemic steroid exposure in the UK (Refractory Asthma & Steroid Exposure)

First published: 08/11/2013

Last updated: 21/02/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/5033

EU PAS number

EUPAS5032

Study ID

5033

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study will use the UK’s Optimum Patient Care Research Database (OPCRD) to address a number of objectives relating to refractory asthma in the UK. The findings of the OPCRD evaluations will be compared to those of the British Thoracic Society's Difficult Asthma Registry morbidity prevalence data to help provide best morbidity prevalence estimates for the UK’s refractory asthma populations and to inform the development of models to estimate the burden of steroid-induced morbidity.The study will consist of two key phases:Phase 1: a cross-sectional matched cohort comparison of morbidity rates in patients with refractory asthma, those with well-controlled asthma and in non-asthmatic controls.Phase 2: a 7-year longitudinal matched cohort comparison of new incidence of morbidities in patients with refractory asthma, well-controlled asthma and non-asthmatic controls.

Study status

Ongoing

Research institutions and networks

Institutions

Queen's University Belfast

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Networks

Respiratory Effectiveness Group (REG)

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

First published: 07/07/2021

Last updated: 04/06/2024

Network | ENCePP partner

Contact details

Study institution contact

Joan Sweeney

Study contact

jsweeney13@qub.ac.uk

Primary lead investigator

Heaney Liam

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/08/2013

Actual: 19/08/2013

Study start date

Planned: 02/09/2013

Actual: 02/09/2013

Date of final study report

Planned: 01/04/2014

Sources of funding

- Other

More details on funding

University, Respiratory Effectiveness Group

Study protocol

Refractory Asthma and oral steroid use_OPCRD study protocol_final281013.pdf (1.09 MB)

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Other

If ‘other’, further details on the scope of the study

Cost effectiveness modelling

Main study objective:

To provide best morbidity prevalence estimates for the UK’s refractory asthma populations to inform models to estimate the burden of steroid-induced morbidity.

Study Design

Non-interventional study design

Case-control

Cohort

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H02AB06) prednisolone

prednisolone

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

30000

Study design details

Data analysis plan

For both Phase 1 and 2 of the study, well-controlled asthma patients and non-asthmatic controls will be matched to refractory asthma patients. To increase the power of the analysis matching will be on a 5-to-1 basis, with five randomly selected well-controlled asthma patients and five non-asthmatic control patients matched to each refractory asthma patients.Matching criteria will be patients': age, gender, year of birth.Phase 1: cross-sectional evaluation: Frequency of existing morbidities in the 2 year period (2011-2013) will be evaluated and reported separately for each group. Rate ratios will be evaluated for each morbidity with 95% confidence intervals. Phase 2: longitudinal evaluation: incidence of new morbidities in the period 1 April 2006–present day will be evaluated for each patient group.Survival analyses will be conducted, patients who are lost to follow up (e.g. through leaving the practice or through death) will be censored.

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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