A prediction model for future exacerbation risk in children

First published: 24/02/2017

Last updated: 08/08/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17985

Study ID

31045

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Asthma attacks in children are common and result in considerable morbidity and occasionally mortality. Additionally, childhood asthma attacks may adversely affect their education, their parents economic productivity and

always incur costs to the healthcare system. Remarkably little is understood about factors which predict childhood asthma attacks and much of what is known is derived from relatively small clinical trials in countries other than the UK and the results may not be generalisable. The present analysis will use routinely acquired data collected in primary care in the UK to identify factors associated with asthma attacks in children. Predictive variables will include demographics (the child's age and sex), asthma characteristics (severity, control and past attacks) and physiological measurements (obesity, lung function and blood eosinophil count). Blood and airway eosinophilia are both risk factors for asthma attacks in adults and whilst the latter would be preferable, this is not routinely collected whereas blood eosinophil count is often measured and is used in this analysis.

Study status

Finalised

Research institutions and networks

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

Steve Turner enquiries@regresearchnetwork.org

Study contact

enquiries@regresearchnetwork.org

Primary lead investigator

Steve Turner

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/02/2017

Actual: 03/02/2014

Study start date

Planned: 24/02/2017

Actual: 24/02/2014

Date of final study report

Planned: 28/04/2017

Actual: 23/09/2014

Sources of funding

- Other

More details on funding

Respiratory Effectiveness Group

Study protocol

REG Study Protocol_Future Risk of Asthma Exacerbations_FINAL.pdf (434.4 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 type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The aim of this study is to create a tool to predict which paediatric patients are at risk of future exacerbation.

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

Patients with following criteria were included:

• Valid blood eosinophil count expressed as a numeric value ≤5000 blood eosinophils/µl, recorded at least 1 year prior to the end of available data

• Aged 5-12 years at date of last valid blood eosinophil count

• An asthma diagnosis (at any time)

• 2 years of continuous data (one year pre/ one year post date of last valid blood eosinophil count).

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

5000

Study design details

Outcomes

1. Exacerbations:An exacerbation is defined as the occurance of the following: • Respiratory-related hospital attendance / admission AND/OR• Respiratory-related A&E attendance AND/OR• An acute oral corticosteroids course, 2. Blood

eosinophil count3. Percent Predicted Peak Flow 4. Number of GP consults for lower respiratory tract infections5. Acute oral steroid usage6. Hospital in-patient admissions

---

Data analysis plan

Univariable logistic regression models will be used to identify baseline measures of disease severity, patient demographics and comorbidities predictive of future exacerbations. The dichotomous variable indicating an exacerbation during the outcome period (YES/NO) will be used as the dependent variable with each measure of disease severity, patient demographic and comorbidity as an explanatory variable. Those variables which show an association ($p < 0.05$) with future exacerbation will be entered into a multivariable model and step-wise reduced to produce a final list of non-collinear predictors of one or more future exacerbations. Results will be presented as odds ratios (OR) with 95% confidence intervals (95% CI).

Data management

ENCePP Seal

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 source(s)

Clinical Practice Research Datalink

Optimum Patient Care Research Database

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