Using real-life patient records to help identify predictors of future exacerbation risk (Asthma risk predictors)

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/26292

EU PAS number
EUPAS4869

Study ID
26292

DARWIN EU® study
No

Study countries
United Kingdom

Study description
Background: Increased understanding of exacerbation patterns and the individual and clusters of risk factors associated with them could help to define ‘frequent exacerbators’ more meaningfully (e.g. as a persistent group of patients at the high end of the control continuum, or a dynamic group population made up of patients experiencing disease phases during which their exacerbation risk is elevated due to specific triggers). Improved understanding of the relationships between patient characteristics and frequent exacerbation risk will help to inform the development of new assessment tools, treatment strategies and interventions aimed at reducing the significant morbidity (and cost)

associated with asthma exacerbations.This study aims to identify patient characteristics recorded within routine primarycare datasets that are associated with increased risk of frequent asthmaexacerbations, with the ultimate goal of:1. Characterising the frequent exacerbator subgroup of asthma patients2. Identifying individual risk factors associated with increased futureexacerbation risk3. Exploring clusters of risk factors associated with increased risk of futureexacerbation risk.

Study status
Finalised

Research institution and networks

Institutions

Research in Real Life
First published: 01/02/2024
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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

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Study timelines

Date when funding contract was signed
Planned:
08/10/2013
Actual:
02/12/2013

Study start date
Planned:
06/01/2014
Actual:
06/01/2014

Date of final study report
Planned:
30/04/2014
Actual:
31/12/2014

Sources of funding

- Other

More details on funding

Respiratory Effectiveness Group (REG), Research in Real Life Ltd

Study protocol

Asthma risk characterisation_REG study proposal_12Nov13.pdf(1.8 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 topic:
Disease /health condition

Study type:
Non-interventional study

Scope of the study:
Disease epidemiology

Data collection methods:
Secondary data collection

Main study objective:
To identify patient characteristics recorded within routine primary care datasets that are associated with increased risk of frequent asthma exacerbations with a view to building a risk assessment model to "Score" patients in terms of their future exacerbation risk.

Study Design

Non-interventional study design
Cohort
Cross-sectional

Study drug and medical condition

Medical condition to be studied
Asthma

Population studied

Short description of the study population
Patients aged 12–80 years who have physician diagnosed asthma and ?3 years of continuous medical records.

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)

Special population of interest
Other

Special population of interest, other
Asthma patients

Estimated number of subjects
50000

Study design details

Outcomes
Co-primary outcomes:• Moderate-to-severe exacerbations: based on the ATS/ERS taskforce definition, any of:(i) Asthma-related: a. Hospitalisations (inpatient admissions) OR b. A&E attendance OR(ii) Use of acute oral steroids• Clinical exacerbations: As above, but including asthma-related out-patient-department attendance and antibiotics for lower respiratory tract infections. Disaggregate components of exacerbation definitions:• Oral steroid prescriptions• Hospitalisations for asthma or lower respiratory conditions• A&E attendance for asthma or lower respiratory conditions• Antibiotic prescriptions for lower respiratory tract infections (LRTIs)

Data analysis plan
Phase 1. Autocorrelation plots will be examined to assess seasonality and timedependent relationships in the rate of exacerbations as described in the methods section.Phase 2 & 3. Univariate (phase 2) and multivariate (phase 3) associations will be estimated using:(i) Negative binomial regression models: will be used to determine predictors offuture risk in terms of severe exacerbation rates over subsequent 1 & 2yrs.(ii) Ordinal logistic regression

models: will be used when annual exacerbationsare categorised 0, 1 and ?2.(iii) Logistic regression models: will be used when severe exacerbations isdefined as a binary outcome. Here, population attributable risks will beestimated to provide an estimation of the proportion of “frequentexacerbation” trait that is explained by each statistically significant factor inthe multivariate models.Phase 4. Hierarchical multi-level modelling will be used to estimate associationswith exacerbation rates.

Data management

Data sources

Data source(s), other
Optimum Patient Care Research Database (OPCRD)

Data sources (types)
Electronic healthcare records (EHR)
Other

Data sources (types), other
Prospective patient-based data collection, The Optimum Patient Care Research Database (OPCRD). OPCRD contains all records from primary care practices in the UK who subscribe to the Optimum Patient Care (OPC) respiratory review. The dataset consists of both routine primary care electronic patient records + patient-reported questionnaire data (for a subset of patients who completed disease-specific questionnaires as part of the review).

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