Development and validation of a risk prediction tool for oral corticosteroid adverse outcomes in asthma, based on real-world exposure information

First published: 14/10/2024

Last updated: 17/10/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000336

Study ID

1000000336

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This study used Optimum Patient Care Research patient records (Jan 1990 to Jun 2021) to develop models for predicting the risk that adults with active asthma at an index visit would have post-index onset of 18 adverse outcomes known to be associated with exposure to oral corticosteroids (OCS), based on independent risk factors known to be associated with these outcomes and projected longitudinal changes in OCS exposure (ie, decreased, unchanged, or increased).

Study status

Finalised

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**

Networks

Optimum Patient Care (OPC) Network

☐ United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated: 16/06/2025

Network | ENCePP partner

Contact details

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Study timelines

Date when funding contract was signed

Planned: 30/03/2020

Actual: 30/03/2020

Study start date

Planned: 30/03/2020

Date of final study report
Planned: 28/05/2020

Actual: 20/12/2023

Sources of funding

- Non-for-profit organisation (e.g. charity)
- Pharmaceutical company and other private sector

More details on funding

Research part funded by AstraZeneca and the Observational and Pragmatic Research Institute.

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Method development or testing

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Data from UK asthma patients were used to track longitudinal changes in oral corticosteroid (OCS) use; the
largest pre–post visit change defined an index date. Risk of OCS-associated morbidities was modelled in cohorts
without pre-index diagnoses using Cox regression and survival time analyses.

Main study objective:

Predict future risks of oral corticosteroid-related morbidities in patients with asthma at differing projected levels
of oral corticosteroid exposure.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Historic longitudinal observational follow-up

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H02) CORTICOSTEROIDS FOR SYSTEMIC USE

CORTICOSTEROIDS FOR SYSTEMIC USE

Medical condition to be studied

Asthma

Population studied

Short description of the study population

United Kingdom adult (age 18-93) primary care patients with asthma registered in the Optimum Patient Care Research Database between January 1990 and June 2021.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 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

Patients with active asthma

Estimated number of subjects

249226

Study design details

Setting

United Kingdom primary care electronic medical records from Jan 1990 to Jun 2012:

Inclusion criteria:

• Minimum 2 years of baseline dataplus at least 3 years of follow-up.

• Active asthma: 2+ prescriptions for asthma medication within1 year before + 1 year after the index visit.

• Age 18-90 at index date (approximate as only birth year is available).

Outcomes

Anxiety/depression; increased body mass index; cataracts; cerebrovascular accident; cerebro-cardiovascular
disease (any among: cerebrovascular accident, heart failure, myocardial infarction); dyslipidaemia; glaucoma;
heart failure; hypertension; myocardial infarction; osteoporosis; osteoporotic fractures; peptic ulcer; pneumonia;
renal impairment (chronic kidney disease stage ≥3a); type 2 diabetes; sleep apnoea

Data analysis plan

Prediction models, regression and survival time-models will be used. Risk factors and secondary risk factors
identified during literature review will be evaluated for inclusion by backward stepwise selection using the Cox
Proportional Hazards Model. Analyses will be performed on 75% of each risk cohort as a training dataset to allow
validation in the remaining 25%.

Summary results

249,226 patients with asthma met eligibility criteria for risk modelling. The pre-index to post-index OCS usage
category remained unchanged in 38.6% of patients, increased in 39.2%, and decreased in 22.2%, with 20.7%
having no further OCS prescriptions . In models, the risks of all adverse outcomes increased with projected
categoric OCS use; for example, hazard ratios for a one-category increment (none to low, low to high) were
1.55 (1.42-1.69) for type 2 diabetes, 1.56 (1.36-1.78) for post-menopausal osteoporosis, 1.05 (1.00-1.10) for
hypertension, and 1.67 (1.52-1.83) for pneumonia (all p <0.001).

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.

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