

Drug utilisation studies using data mapped to the OMOP Common Data Model: a proof of concept study assessing respiratory drug use in patients with asthma or COPD

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Study

Ongoing

Administrative details

EU PAS number

EUPAS41726


Study ID

42388

DARWIN EU® study

No

Study countries

 Netherlands

 United Kingdom

 United States

Study description

The use of healthcare data, generated through the delivery of normal clinical care is increasingly being proposed as a source of evidence to support not only drug development and regulatory decision-making but also to understand the physiology and pathogenesis of diseases. Use of multiple electronic health care databases is important not only to increase sample size but also to investigate country specific differences, differences by type of databases (e.g. primary vs. secondary care) or to replicate findings. One of the challenges however are the differences between the databases with regard to the underlying structures and semantic mapping. A common data model could help harmonise healthcare data across multiple data sets and provide a mechanism to allow the conduct of multi-database, international studies. The European Health Data and Evidence Network (EHDEN) project (<https://www.ehden.eu/>) is an international project supported by the Innovative Medicines Initiative (IMI) aiming to standardize health care data to the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) and to develop and implement tools to facilitate research on large electronic health care databases. One of the objectives of the EHDEN project is to test existing methodologies but also to develop new methodologies and analytical tools to conduct (pharmaco)epidemiological research using electronic health care databases mapped to the OMOP CDM. To investigate the validity and functionality of this approach, we want to conduct a drug-utilisation study using EHR data. As proof of concept study we want to conduct a drug utilisation studies on respiratory drug use in patients with asthma and chronic obstructive pulmonary disease (COPD). This research is important and relevant as asthma and COPD are prevalent conditions, primarily treated in primary care.

Study status

Ongoing

Research institutions and networks

Institutions


Erasmus Medical Centre Rotterdam

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Institution

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

 United Kingdom

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Institution

Educational Institution

Hospital/Clinic/Other health care facility

NDORMS Oxford - UK

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Katia Verhamme

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2018

Actual: 01/11/2018

Study start date

Planned: 01/01/2010

Actual: 01/01/2010

Data analysis start date

Planned: 01/11/2021

Date of final study report

Planned: 01/01/2022

Sources of funding

- EU institutional research programme

More details on funding

IMI - EHDEN

Study protocol

[DUS_asthmaCOPD_full_protocol_2july2021.pdf](#) (763.4 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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

By means of a drug utilisation study we want to investigate:

- The frequency of respiratory drug use in terms of prevalence and incidence of use
- Treatment pathways in particular treatment step-up and treatment step-down
- To investigate switching between respiratory drugs
- To investigate treatment

adherence

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03D) OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Medical condition to be studied

Asthma

Chronic obstructive pulmonary disease

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

1000000

Study design details

Data analysis plan

1/ Drug use will be assessed per respiratory class as a whole presented as prevalent and incident drug use. For prevalent drug use, the nominator consists of all patients with at least one day of exposure to the drug of interest in the calendar year. The denominator consists of all patients contributing at least one day of observation time in that calendar year. For the incidence drug use calculation, the nominator consists of the number of incident users in the year. 2/ This study will describe the treatment pathways of patients diagnosed with asthma, COPD or ACO. The analysis will calculate the aggregate summary statistics for each diagnosis cohort to determine the treatment pathway for each of the respiratory drugs in the study. 3/ Adherence will be assessed using 2 measures of adherence namely the medication possession ratio (MPR) and the proportion days covered (PDC).

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
Integrated Primary Care Information (IPCI)

Data source(s), other

CPRD, IPCI

Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Electronic healthcare records \(EHR\)](#)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings**CDM name**

OMOP

CDM website

<https://www.ohdsi.org/Data-standardization/>

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No