Comparing Database Harmonisation Methods Applied to Real-World Electronic Healthcare Data

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/104220

EU PAS number

EUPAS104219

Study ID

104220

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

The use of multiple health databases is the preferred method for generating evidence on the safety and effectiveness of medicines, compared to the use of a single database. However, these larger studies have an additional number of complexities. These are in part due to the heterogeneity amongst data sources, a challenge only amplified when using internationally distributed databases. Harmonisation methods such as the use of a common protocol (CP) and/or a common data model (CDM) can improve consistency of findings across databases. Here we will compare different harmonisation methods by comparing the subsequent effect estimates and summary measures in an applied internationally distributed database setting.

Study status

Planned

Research institutions and networks

Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

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Institution **Educational Institution** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicholas Hunt

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2019

Actual: 01/09/2019

Study start date

Planned: 01/06/2023

Date of final study report

Planned: 01/10/2023

Sources of funding

- Other

More details on funding

PhD project

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:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The objective is to assess whether the implementation of a study specific CDM and a general CDM, versus using a common protocol alone has an impact on the consistency of the study results of a pharmacoepidemiologic study in real-world data.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AA) Vitamin K antagonists

Vitamin K antagonists

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AF) Direct factor Xa inhibitors

Direct factor Xa inhibitors

Medical condition to be studied

Haemorrhage

Ischaemic stroke

Acute myocardial infarction

Glaucoma

Population studied

Age groups

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

44000

Study design details

Outcomes

TBC, TBC

Data analysis plan

TBC

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

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

No