Validation of predictors for oral anticoagulant medication choice using EMR data

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/16315

EU PAS number

EUPAS16314

Study ID

16315

DARWIN EU® study

No

Study countries

☐ United States

Study description

This validation study seeks to ascertain a select set of covariates in electronic medical records (EMRs) linked to a subset of patients within the insurance claims data in order to assess the potential for unmeasured confounding in observational studies based on insurance claims databases only.

Study status

Planned

Research institutions and networks

Institutions

Brigham and Women's Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sebastian Schneeweiss

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/06/2012

Actual: 01/06/2012

Study start date
Planned: 06/01/2017

Data analysis start date
Planned: 06/01/2017

Date of final study report
Planned: 30/09/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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:

Other

If ‘other’, further details on the scope of the study

Validation Study

Main study objective:

To identify select clinical covariates from electronic medical records that might be associated with initiation of oral anticoagulant medications. To quantify the association between EMR-based clinical characteristics and patterns of insurance claims. To assess the potential for unmeasured confounding in dabigatran vs warfarin comparative effectiveness and safety studies based on claims data

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Validation Study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01A) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Medical condition to be studied

Atrial fibrillation

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

60000

Study design details

Outcomes

Obesity Smoking Alcohol consumptionAbnormal renal function Bleeding history or predispositionRenal function (estimated GFR)Serum CreatinineAbnormal liver function, Duration of atrial fibrillation History of adherenceHypertensionUncontrolled Hypertension (for HAS-BLED)Congestive heart failurePrior TIA DiabetesHyperlipidaemiaHAS-BLED ScoreUse of anti-platelets or NSAIDs (needed for HAS-BLED)

Data analysis plan

Analyses will characterize patients with EMR and compare them to those without EMR to assess representativeness of the linked sample. To identify covariates from EMR that might be associated with initiation of oral anticoagulants, the presence of EMR-based clinical characteristics among initiators of dabigatran and warfarin will be described. To quantify the association between EMR-based clinical characteristics and patterns of insurance claims, a prediction algorithm will be estimated using a regression model that uses each of the EMR characteristic as the model outcome and all available claims-based covariates as predictors. To assess the potential for unmeasured confounding, logistic regression models that predict exposure (dabigatran vs. warfarin) with claims data only, EMR data only, and both, will be fitted.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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