Medical Need of Non-vitamin K Oral Anti-coagulant Reversal in Japan: Epidemiological Assessment of Emergency Surgery, Trauma and Fracture, using Large Scale Claims Database

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20054

EU PAS number

EUPAS20053

Study ID

20054

DARWIN EU® study

No

Study countries

Japan

Study description

The primary objective of this study is to assess the incidence rates of emergency surgery and major bleeding associated with fracture and trauma. Secondary objective is to assess the incidence rates of cardiac tamponade and pericardiocentesis.A further objective is to describe the types of emergency surgeries identified

Study status

Planned

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

Yasuhisa Ono

Study contact

yasuhisa.ono@boehringer-ingelheim.com

Primary lead investigator

Yasuhisa Ono

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/08/2017

Study start date
Planned: 28/07/2017

Date of final study report
Planned: 29/09/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim

Study protocol

20170714_PROTOCOL-Trauma_Surgery final_edit.pdf(388.49 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:

Disease epidemiology

Main study objective:

The primary objective of this study is to assess the incidence rates of emergency surgery and major bleeding associated with fracture and trauma. Secondary objective is to assess the incidence rates of cardiac tamponade and pericardiocentesis.A further objective is to describe the types of emergency surgeries identified

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

DABIGATRAN

RIVAROXABAN

EDOXABAN

APIXABAN

WARFARIN

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

62888

Study design details

Outcomes

For the primary objectiveIncidence rate (overall and age stratified) of emergency surgery and major bleeding due to fracture/trauma will be described with number of patients presenting the event, patient-years and 95% confidence interval overall and stratified by age. For the secondary objectiveIncidence rates (overall and age stratified) of cardiac tamponade and peri-cardiocentesis, along with number of events, patient year of follow-up not including time after switch, and 95% confidence interval. For the further objective

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Data analysis plan

Incidence of emergency surgery, major bleeding due to fracture and trauma during the on-treatment follow-up in the claims database with number of patients presenting the event, patient-years and 95% confidence interval overall and stratified by age.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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