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

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

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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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Non-interventional study based on existing health insurance claims data.

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

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AF01) rivaroxaban

rivaroxaban

(B01AF03) edoxaban

edoxaban

(B01AF02) apixaban

apixaban

(B01AA03) warfarin

warfarin

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Inclusion criteria

1. >18 year old non-valvular atrial fibrillation (NVAF) patients

2. Prescribed dabigatran, rivaroxaban, apixaban, edoxaban or warfarin

3. Patients with confirmed date of initiation of OACs

4. Patients with a minimum of 6 months of enrolment data prior to index date

5. Has an index date between 14th of March 2011 to 30 June, 2016

Exclusion criteria

1. Patients receiving two or more oral anti-coagulants at the same time at index date

2. Patients with prescriptions of index treatment in the 6 months prior to index date

3. Patients without enrolment period of at least six month in the database

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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

Setting

MDV clinical database is used.

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.

Summary results

The number of patients meeting the inclusion and exclusion criteria was 53,969. The age (average±standard deviation (SD)) and percentage of female in these patients were 76±10 with 40% female. Followings are the
results of the analyses which included time after switch of OAC. Age stratified data are described in parenthesis. The number of patients with emergency

surgery or major bleeding due to fracture/trauma was 133 (14, 35, and 84 for the patient group with age <=64, 65-74 and >=75, respectively). The number of patients with cardiac tamponade and pericardiocentesis was 1. The number of patients with emergency surgery of cardiovascular system was 30 (2, 9, and 19 for the patient group with age <=64, 65-74 and >=75, respectively). The number of patients with emergency surgery of abdomen was 39 (5, 10, and 24 for the patient group with age <=64, 65-74 and >=75, respectively). The number of patients with emergency surgery of urinary system/adrenal glands was 3 (1, 2, and 0 for the patient group with age <=64, 65-74 and >=75, respectively).
Comparable results were obtained from analyses which excluded time after switch of OAC. Patient characteristics showed that arterial hypertension was the most frequent diseases within 6 months baseline period. The average±SD of Charlson co-morbidity index was 1.7±2.1. As concomitant medication with OAC, amiodarone and clopidogrel were prescribed in less than 10% of the patients, whereas the other investigated medications were prescribed in over 10 % of the patients.

Documents

Study results

1321-0022_Synopsis.pdf (158.02 KB)

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 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