A retrospective cohort study with chart review to assess the management of major bleeding events in NVAF patients treated with dabigatran etexilate

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/9981

EU PAS number

EUPAS6568

Study ID

9981

DARWIN EU® study

No

Study countries

United States

Study description

This will be an observational chart review study. Details of major bleeding events will be abstracted from medical records using a standardized data collection tool (electronic case report form (eCRF)).

Study status

Planned

Research institutions and networks

Institutions

inVentive Health

First published: 01/02/2024

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Institution

Brigham and Women's Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

State University of New York Stony Brook, NY, Maimonides Medical Center New York, Brigham and Women's Hospital Boston, Seton Health Center Texas, Beth Israel Deaconess Medical Center Boston

Contact details

Study institution contact

Health Clinical inVentiv

Study contact

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Primary lead investigator

Health Clinical inVentiv

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/04/2014

Study start date

Planned: 30/05/2014

Date of final study report
Planned: 20/03/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Pharmaceuticals Inc.

Regulatory

Was the study required by a regulatory body?

No

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

Assessment of management of major bleeding

Main study objective:

The objective of this non interventional study is to assess the clinical characteristics of major bleeding events in patients with NVAF taking dabigatran who present to emergency departments/emergency rooms or who are hospitalized in-patients for management of such events.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

200

Study design details

Outcomes

1) Number of patients with index event (ongoing/resolved/deceased) at time of hospital discharge/release, 2) Frequencies of patients receiving different types of interventions to stop index event until hospital discharge and 3) Frequencies of bleeding types and anatomic locations of the index events at time of ED/ER presentation.

Data analysis plan

Descriptive analyses frequencies, means, standard deviations, medians, ranges, minimum and maximum values, 95% confidence intervals and proportions, as appropriate) of patient characteristics, bleeding sources, diagnostic approaches, type of interventions for treatment of bleeding and outcome of the interventions overall and by relevant demographic and intervention subgroups supplemented with a compilation of narratives describing the bleeding. Narratives will be generated from a standard template into which data will be entered from the database.Subgroup analyses of interest will be based upon pertinent clinical criteria such as age, sex, body-mass index, dabigatran etexilate dose (and retrospective determination of appropriateness of dose), treatment duration, concomitant medications (specifically antiplatelet agents and P-glycoprotein (P-gp) inhibitors), past medical history (e.g. prior history of bleeding events), and renal function.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective cohort study with chart review using electronic medical records

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