Patients' Assessment of Satisfaction for Stroke Prevention in Atrial Fibrillation --- Impact of Conventional Oral Anticoagulant (OAC) Compared With Novel Oral Anticoagulant (NOAC) (PASSION)

First published: 19/06/2017

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Study Ongoing

Administrative details

EU PAS number

EUPAS19558

Study ID

28205

DARWIN EU® study

No

Study countries

☐ Taiwan

Study description

To describe the treatment perception from patients with non-valvular atrial fibrillation (NVAF) receiving Pradaxa® or VKA for stroke prevention by using the self-estimation questionnaire of PACT-Q during a 6-month study period.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

John.chang@boehringer-ingelheim.com

Primary lead investigator

John Chang

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 19/06/2017

Study start date

Planned: 19/06/2017

Actual: 20/06/2017

Data analysis start date

Planned: 30/06/2017

Actual: 23/06/2017

Date of final study report
Planned: 31/12/2019

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:

Disease epidemiology

Main study objective:

Objective 1 To describe the treatment perception from patients with non-valvular atrial fibrillation (NVAF) receiving Pradaxa® or VKA for stroke prevention by using the self-estimation questionnaire of PACT-Q during a 6-month study period. Objective 2 To investigate the patient’s characteristics.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

PRADAXA

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

1000

Study design details

Outcomes

Cohort A (patients switched from VKA to Pradaxa) Mean PACT-Q2 scores at the second (30-45 days) and the last assessment (150-210 days) compared to baseline assessment. Cohort B (patients newly initiated Pradaxa or VKA) Mean PACT-Q2 scores at the second (30-45 days) and the last assessment (150-210 days) compared between 2 treatment groups. Cohort A (patients switched from VKA to Pradaxa) Mean PACT-Q2 score at the last assessment (150-210 days) compared to the second assessment (30-45 days). Cohort B (patients newly initiated Pradaxa or VKA) Description of mean PACT-Q1 score at baseline.

Data analysis plan

Baseline demographic and clinical characteristics Descriptive summary will be presented for baseline demographic and clinical characteristics of all patients enrolled in Cohort A, Cohort B Pradaxa® initiators, and Cohort B VKA initiators, respectively. For continuous variables, number of patients, mean, standard deviation (SD), median, Q1 (lower quartile), Q3 (upper quartile), minimum, and maximum will be presented. For categorical variables, frequency and percentage will be presented for each category.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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