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

Last updated: 16/10/2026

Study Finalised

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

Finalised

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

Actual: 27/06/2019

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

Other study registration identification numbers and links

1160-0286; NCT03187197

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

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

Medicinal product name

PRADAXA

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

DABIGATRAN ETEXILATE

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

Population studied

Short description of the study population

Patients with non-valvular atrial fibrillation (NVAF) receiving Pradaxa® or VKA for stroke prevention

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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

1.000

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.

Documents

Study results

1160-0286_Synopsis.pdf (219.65 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)

Patient surveys

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