Non-interventional study describing treatment convenience in patients treated with Dabigatran for Stroke Prophylaxis in Atrial Fibrillation (SPAF) (RE-SONANCE)

First published: 03/06/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13672

Study ID

32059

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Describe patient and physician assessed factors for patient well-being when treated with Pradaxa for stroke and embolism prevention in atrial fibrillation either compared to previous antithrombotic treatment (switcher)

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 200 centres are involved in the study

Contact details

Study institution contact

Mireia Canals mireia.canals@boehringer-ingelheim.com

Study contact

mireia.canals@boehringer-ingelheim.com

Primary lead investigator

Barrios Vivencio

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2015

Actual: 01/11/2015

Study start date

Planned: 13/06/2016

Actual: 28/06/2016

Data analysis start date

Planned: 05/11/2018

Actual: 03/12/2018

Date of final study report

Planned: 30/09/2019

Actual: 20/09/2019

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

Describe the non-valvular AF patient well-being by using the PACTQ-2 at three time-points when (1) being treated with any anticoagulation therapy to prevent stroke/embolism and planned to be switched (baseline to capture VKA treatment perception) when (2) being initiated on Pradaxa® (30-45 days) and (3) continued on Pradaxa® (~180 days).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, observational study

Study drug and medical condition

Name of medicine

PRADAXA

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Patients in Spain with NVAF who were treated with VKAs and subsequently started Pradaxa®, and who gave their consent.

Patients should met all the following inclusion criteria:

1. Granting informed consent in writing prior to enrolment.
2. Patients of both sexes ≥ 18 years of age with a diagnosis of NVAF.
3. Patients treated continuously with VKAs for stroke prophylaxis for at least six months prior to the baseline visit.
4. Patients switching to treatment with Pradaxa® in accordance with the recommendations of the competent health authorities described in the therapeutic positioning report for NOACs and the authorisations of the various autonomous communities

---

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)

Special population of interest

Other

Special population of interest, other

Atrial fibrillation patients

Estimated number of subjects

1087

Study design details

Outcomes

Outcome 1: Mean PACT-Q2 scores at second and last assessment compared to baseline assessment.Outcome 2: Mean PACT-Q2 score at last assessment compared to second assessment. Characterization of patients according to: Age, Gender, CHA2DS2-VASc score, HAS-BLED score, creatinine clearance, Stroke and/or bleeding related risk factors in medical history and at baseline, Concomitat diseases, Concomitant therapies, Dosing of Pradaxa®, Duration of previous VKA treatment

---

Data analysis plan

In this non-interventional study, cross-sectional data at study baseline and longitudinal follow-up data over 6 months will be collected for non-valvular AF patients with a current VKA therapy and subsequent initiation of Pradaxa®. Baseline data will be described using a cross-sectional approach. Data from the longitudinal follow-up will be summarized descriptively.

Documents

Study results

1160-0253-non-interventional-study-report-abstract.pdf (232.05 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)

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