Non-interventional study describing patients´ perception on anticoagulant treatment and treatment convenience when treated with Pradaxa or Vitamine K Antagonist for Stroke Prevention in Non-Valvular Atrial Fibrillation (Patient convenience study (RE-SONANCE))

First published: 21/12/2015

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/11925

EU PAS number

EUPAS11924

Study ID

11925

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Bulgaria
- [ ] Czechia
- [ ] Estonia
- [ ] Hungary
- [ ] Israel
- [ ] Latvia
- [ ] Poland
- [ ] Romania
- [ ] Russian Federation
- [ ] Serbia
- [ ] Slovenia

Study description

The aim of this study is to describe how patients with non-valvular atrial fibrillation (NVAF)perceive anticoagulant treatment with Pradaxa (dabigatran etexilate) for stroke prevention incomparison to treatment with Vitamin K Antagonist (VKA). Two different groups (cohorts) ofpatients will be investigated:Cohort A: NVAF patients who used VKA for at least 3 months prior to study enrolment andare switched to Pradaxa.Cohort B: newly diagnosed NVAF patients who are initiated to either Pradaxa or VKAtreatment upon study enrolment.

Study status

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

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Primary lead investigator

Boehringer Ingelheim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/03/2015

Actual: 27/03/2015

Study start date

Planned: 30/11/2015

Actual: 27/11/2015

Data analysis start date
Planned: 13/01/2017

Date of final study report
Planned: 31/05/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim RCV GmbH & Co KG

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:

Drug utilisation

Main study objective:

To describe how patients with non-valvular atrial fibrillation (NVAF)preceive anticoagulant treatment, with Pradaxa or VKA, for stroke prevention, using the PACT-Q questionnaires.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

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

9000

Study design details

Outcomes

For Cohort A (NVAF patients on VKA who are switched to Pradaxa®): Mean PACT-Q2 scores at second and last assessment compared to baseline assessment.For Cohort B (newly diagnosed NVAF patients initiated to either VKA or Pradaxa®): Mean PACT-Q2 scores at second and last assessment compared between treatment groups. For Cohort A (patients switched to Pradaxa®): Mean PACT-Q2 scores at last assessment compared to second assessment.For Cohort B (patients newly initiated to VKA or Pradaxa®):Description of PACT-Q1 items at baseline.

Data analysis plan

In this non-interventional 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® in Cohort A, and for newly diagnosed AF patients initiated on Pradaxa® or VKA in Cohort B.Data from baseline and the longitudinal follow-up will be summarized descriptively. For Cohort A, mean PACT-Q2 scores between assessments will be compared using paired t-tests.

For Cohort B, mean PACT-Q2 scores between Pradaxa® and VKA patients will be compared using propensity score matched analysis.

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