Non-interventional study describing patients´ perception on anticoagulant treatment and treatment convenience when treated with Pradaxa or Vitamin K Antagonist for Stroke Prophylaxis in Atrial Fibrillation (1160.247 (RE-SONANCE))

First published: 11/11/2015

Last updated: 17/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS10457

Study ID

31059

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Denmark
- [ ] Greece
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Sweden

Study description

RE-SONANCE is a multi-national, multi-center non-interventional study based on new data collection. 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 in comparison to treatment with Vitamin K Antagonist (VKA). Two different groups (cohorts) of patients will be investigated: - Cohort A: NVAF patients who used VKA for at least 3 months prior to study enrolment and are switched to Pradaxa.- Cohort B: newly diagnosed NVAF patients who are initiated to either Pradaxa or VKA treatment upon study enrolment.The patients will be followed up after approximately 1 month and 6 months of treatment with Pradaxa or VKA to collect the Perception of Anticoagulant Treatment Questionnaire (PACT-Q) and safety data.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 150 centres are involved in the study

Contact details

Study institution contact

Boehringer Ingelheim clintriage.rdg@boehringer-ingelheim.com

Study contact

clintriage.rdg@boehringer-ingelheim.com

Primary lead investigator

Robert Tieleman

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/07/2015

Actual: 17/07/2015

Study start date
Planned: 08/09/2015

Actual: 11/11/2015

Data analysis start date
Planned: 26/01/2017

Actual: 30/05/2017

Date of final study report
Planned: 15/01/2019

Actual: 24/07/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1160-0247_protocol_redacted.pdf (1.07 MB)

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:

Other

If ‘other’, further details on the scope of the study

Evaluation of the patients perception on anticoagulant treatment, including convenience, burden of disease and treatment and treatment satisfaction

Data collection methods:

Primary data collection

Study design:

Non-interventional study of NVAF patients in Europe who were using VKA therapy and were switched to Pradaxa®
therapy OR patients who were newlydiagnosed with NVAF and initiated on Pradaxa® or VKA.

Main study objective:
To describe how patients with non-valvular atrial fibrillation (NVAF)perceive 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

Medicinal product name
PRADAXA

Medicinal product name, other
PRADAXA or Vitamin K Antagonist (VKA)

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

Anatomical Therapeutic Chemical (ATC) code
(B01AA) Vitamin K antagonists

Vitamin K antagonists

(B01AE07) dabigatran etexilate

dabigatran etexilate

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Two different groups (cohorts) of patients will be investigated: - Cohort A: non-valvular atrial fibrillation (NVAF) patients who used VKA for at least 3 months prior to study enrolment and are switched to Pradaxa. - Cohort B: newly diagnosed NVAF patients who are initiated to either Pradaxa or VKA treatment upon study enrolment.

Age groups

- 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

Non-valvular atrial fibrillation (NVAF) patients

Estimated number of subjects

1851

Study design details

Setting

Data of approximately 3.000 patients were planned to be collected from approximately 220 sites in 7 European countries (Belgium, Denmark, Greece, Norway, Portugal, Sweden and The Netherlands).

Outcomes

For Cohort A (NVAF patients on VKA who are switched toPradaxa®): Mean PACT-Q2 scores at second and last assessment compared to baseline assessment.For Cohort B (newly diagnosed NVAF patients initiated to eitherVKA 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.

Documents

Study results

1160-0247_Synopsis.pdf (328.67 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

Unknown