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 (RELATE)

First published: 05/05/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13390

Study ID

26437

DARWIN EU® study

No

Study countries

Indonesia

Korea, Republic of

Malaysia

Singapore

Thailand

Viet Nam

Study description

The aim of this non-interventional study is to describe patient's perception of anticoagulant treatment when using Pradaxa® to prevent stroke and systemic embolism while suffering from atrial fibrillation (according to its approved indication in the approved dosages of 110 mg or 150 mg twice daily) in comparison to standard care using Vitamin K Antagonist (VKA).

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

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Institution

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Peak Yuen Lee

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/05/2016

Actual: 03/06/2016

Study start date

Planned: 05/06/2016

Actual: 24/06/2016

Data analysis start date

Planned: 11/01/2018

Actual: 22/01/2018

Date of final study report
Planned: 30/09/2018

Actual: 28/10/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1160 261-clinical-trial-protocol-final-25 Jan 16.pdf (710.37 KB)

1160 261-clinical-trial-protocol-final-25 Jan 16_Redacted.pdf (714.68 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

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 atrial fibrillation patient´s treatment perception by using the PACT-Q at three time-points at baseline, during initiation period and during the continuation period.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PRADAXA

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Patients aged 18 years and older with non-valvular atrial fibrillation (AF) in South East Asia South Korea (SEASK) with a current Vitamin K Antagonist (VKA) therapy and subsequent initiation of Pradaxa® (Cohort A) OR patients being newly diagnosed with AF and initiated on Pradaxa® or VKA (Cohort B).

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

1385

Study design details

Outcomes

Primary outcomeFor Cohort A (switcher):- Mean PACT-Q2 scores at second and last assessment compared tobaseline assessmentFor Cohort B (newly initiated):- Mean PACT-Q2 scores at second and last assessment between treatment groups, Secondary outcome:For Cohort A (switcher):- Mean PACT-Q2 score at last assessment compared to second assessmentFor Cohort B (newly initiated):- Description of PACT-Q1 items at baseline

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Data analysis plan

Baseline data will be analyzed using a descriptive approach. Data from the longitudinal follow-up will be summarized descriptively. For Cohort A, mean differences in PACT-Q2 scores between assessments will be assessed using paired t-tests. For Cohort B, mean differences in PACT-Q2 scores between Pradaxa® and VKA patients will be assessed using propensity score matched analysis.Due to the nature of this non-interventional study, there is no (confirmatory) hypothesis testing foreseen in a strict statistical sense. Analyses are descriptive in nature and confidence intervals and p-values from statistical models are used for exploratory purposes.

Documents

Study results

CSR for ENCEPP_Redacted.pdf (3.69 MB)

Study publications

Monz BU, Connolly SJ, Korhonen M, Noack H, Pooley J. Assessing the impact of da…

Prins MH, Guillemin I, Gilet H, Gabriel S, Essers B, Raskob G, Kahn SR. Scoring…

De Caterina R, Brueggenjuergen B, Darius H, Le Heuzey JY, Renda G, Schilling RJ…

Lip GY, Nieuwlaat R, Pisters R, Lane DA, Crijns HJ. Refining clinical risk stra…

Pisters R, Lane DA, Nieuwlaat R, De Vos CB, Crijns HJ, Lip GY. A novel user-fri…

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