Relationship of Advanced Holding Education and ADherence on antithrombotic in younger NVAF patients (ReAHEAD)

First published: 18/08/2020

Last updated: 17/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS36807

Study ID

36808

DARWIN EU® study

No

Study countries

Taiwan

Study description

The objective of ReAHEAD study is to explore whether advanced educational interventions would improve adherence to dabigatran, in 12 months follow up period for AFib patients under 75 years old. it is a single country, multi-center, educational intervention randomized study to evaluate the adherence to dabigatran, for up to 12 months. Newly diagnosed patients with atrial fibrillation within 1 month, under 75 years old and newly prescribed with dabigatran on physician’ s decision will be randomized to receive standard of care or standard of care with additional education (1:1). We will measure adherence to dabigatran by MMAS-8 score (Chinese version).

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Vanessa Lei

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/04/2020

Actual: 17/04/2020

Study start date

Planned: 11/09/2020

Date of final study report

Planned: 30/06/2023

Actual: 16/02/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Taiwan Ltd.

Study protocol

1160-0304_protocol_redacted.pdf (1.27 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 additional patient educationa compared with regular clinical practice

Data collection methods:

Primary data collection

Study design:

This was a multi-center, 1:1 randomized study to evaluate the effects of educational intervention on adherence to dabigatran, for up to 12 months. Adult patients newly diagnosed with AF within 1 month, under 75 years old, and newly prescribed with dabigatran on physician’s decision per local lab.

Main study objective:

The study aims to explore whether the advanced educational intervention would improve the adherence to dabigatran.

Study drug and medical condition

Medicinal product name

PRADAXA

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

Medical condition to be studied

Atrial fibrillation

Population studied

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

1200

Study design details

Setting

The study was carried out from 2020 to 2023 at around 23 hospitals, where AF patients were mainly treated in Taiwan. The first patient to be enrolled was from 21-Sep-2020, and the last patient’s last visit was on 26-Jun-2023.
A total of 897 patients were screened and signed the ICF, and 873 patients were eligible to be enrolled in the analysis.

Outcomes

The primary objective of this study is to explore whether the advanced educational intervention would improve the adherence to dabigatran, in a 12-month follow-up period for newly diagnosed atrial fibrillation (AF) adult patients under 75 years old. The secondary objectives are to investigate comorbidities, CHA2DS2-VASc score, and further endpoints in dabigatran patients (with or without advanced educational intervention) in a 12-month follow-up period for AF adult patients under 75 years old.

Data analysis plan

The analyses will be mainly descriptive. All patients who have signed the informed consent and fulfilled study criteria will be included in the main analysis. The primary analysis will describe the proportion of patients with high

adherence to dabigatran treatment at 12 months for each group. Subjects without MMAS-8 value recorded at 12 months will be excluded from the analysis of primary endpoint.Continuous variables will be reported as number, mean, standard deviation (SD), minimum, maximum, and 95% confidence interval (CI). Categorical variables will be summarized as number and frequency or percentage with observed (non-missing) data. For endpoints to be compared between patients with and without advanced educational intervention, the analyses will be done by t-test or Wilcoxon rank-sum test for continuous data, and by Chi-square, Fisher's exact, or other appropriate tests for categorical data. Other endpoints will be analyzed in an exploratory manner.

Documents

Abstract of study report

1160-0304_Synopsis.pdf (409.17 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