Non-Interventional, cross-sectional study to describe health-related quality of life among controlled and uncontrolled patients with nonvalvular atrial fibrillation on anticoagulants (RE-QUOL study)

First published: 30/12/2016

Last updated: 19/10/2026

Study | Finalised

Administrative details

EU PAS number

EUPAS16988

Study ID

32062

DARWIN EU® study

No

Study countries

Spain

Study description

The present study has been designed to describe the HRQoL in patients with non valvular AF receiving conventional VKA but no controlled and those controlled who received VKA or DOAC. Approximately 500 patients seen in internal medicine are planned to be included in the study. Patients should be included in a ratio 2:1, 2 patients controlled (VKA patients with a Time in Therapeutic range TTR ≥ 65% and all DOAC patients) per 1 patient uncontrolled (VKA patients with a TTR < 65%), due to the controlled patients comprise more treatments. The design of the study impose an only visit to be performed that will coincide with one of those performed by the patients as part of routine follow-up of their disease, without interfering with usual clinical practice of the investigator. HRQoL will be based on the patients' ratings on Sawicki questionnaire completed during the only study visit. This questionnaire includes 32 items grouped in 5 dimensions – treatment satisfaction, self-efficacy, strained social network, daily hassles and distress. Higher scores indicate lower HRQoL. The scores of each individual question will be summarized descriptively in thecontrolled and uncontrolled patients.

Study status

Finalised

Research institutions and networks

Institutions

Hospital Costa del Sol

Multiple centres: 50 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

Javier García Alegría

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2016

Actual: 01/11/2016

Study start date

Planned: 30/04/2017

Actual: 26/04/2017

Data analysis start date

Planned: 02/04/2018

Actual: 12/04/2018

Date of final study report

Planned: 31/01/2019

Actual: 28/01/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1160-0280-clinical-trial-protocol-version-01-final-rule_Redacted.pdf (464.29 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

1160-0280

NCT03134911

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Observational multicenter and cross-sectional study

Main study objective:

The primary objective of the study is to describe the HRQoL in uncontrolled patients treated with VKA and controlled patients treated with VKA or DOAC.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

PRADAXA

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

DABIGATRAN ETEXILATE

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Nonvalvular AF (NVAF) patients with uncontrolled anticoagulation status treated with VKA, and of NVAF patients with controlled anticoagulation status treated with vitamin K antagonists (VKA) or direct oral anticoagulants (DOAC).

Inclusion criteria were:

1. The patient is willing and provides written informed consent to participate in this study.

2. The patient is at least 18 years of age.

3. The patient has a diagnosis of non-valvular atrial fibrillation.
4. The patient is on the same anticoagulant therapy (VKA or DOAC) during at least 6 months and maximum 2 years.
5. If treated with VKA, availability of %TTR in past analytical records or enough amount of INR measures to calculate it.

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

Non-valvular atrial fibrillation (NVAF) patients

Estimated number of subjects

500

Study design details

Setting

This study was conducted in the Autonomous Communities of Madrid, Valencia and Andalucía (Spain). Forty-seven internal medicine specialists from 38 Hospital sites regularly prescribing DOACs and VKA for stroke prevention in NVAF according to the respective Summary of Product Characteristics (SmPC)

participated in the study.

Outcomes

The primary outcome is the health-related quality of life and will be obtained with the results of the sawicki questionnaire at study visit. The questionnaire includes 32 itemsgrouped in 5 dimensions. Patients will estimate the impact of each item on their selfperceived treatment-related quality of life on a scale of 1 (total disagreement) to 6 (total agreement). The secondary outcome is the uncontrolled patient profile and will be defined by thefollowing variables collected from patient medical records.

Data analysis plan

The primary outcome of the study is the health-related quality of life as measured by the Sawicki questionnaire. The scores of each individual question will be summarized descriptively in the controlled and uncontrolled patients. In addition, the summary score for each dimension of the questionnaire will be calculated for each patient by dividing the total score by the number of items included in that dimension and summarized in the same way as the individual questions.

Summary results

DISCUSSION

The study presented HRQoL perceptions of NVAF patients on anticoagulants, either controlled or uncontrolled, assessed by the validated Spanish adaptation of the Sawicki questionnaire, which included five different dimensions (general treatment satisfaction, self-efficacy, distress, daily hassles and strained social network). From a descriptive point of view, controlled patients (treated with DOAC or VKA) had mean scores closer to a high perceived HRQoL in the 5 dimensions of the questionnaire, with remarkably high scores for general treatment satisfaction. These results suggest that TTR control might influence

perceptions of HRQoL and highlight the importance of evaluate anticoagulation status, when assessing HRQoL.An understanding of the factors that influence HRQoL is required in order to adapt economic evaluations to the characteristics of a specific patient
population and assess the clinical and cost-effectiveness of different therapeutic alternatives. Our study provided a detailed description of the demographic and clinical profile of uncontrolled NVAF patients on anticoagulants, which should warrant further exploration of the extent to which particular demographic and clinical characteristics of these patients might influence perceptions of their HRQoL.

Documents

Study results

1160-0280_c26547692-01.pdf (243.69 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

Retrospective 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