

# 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:** 31/03/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/32062>

### EU PAS number

EUPAS16988

### Study ID

32062

### DARWIN EU® study

No

## Study countries

☐ Spain

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## 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  $\geq$  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 the controlled and uncontrolled patients.

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## 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

Study contact

[mireia.canals@boehringer-ingenelheim.com](mailto:mireia.canals@boehringer-ingenelheim.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

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### Study start date

Planned: 30/04/2017

Actual: 26/04/2017

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**Data analysis start date**

Planned: 02/04/2018

Actual: 12/04/2018

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**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

## Regulatory

**Was the study required by a regulatory body?**

No

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Combined primary data collection and secondary use of data

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**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

**Name of medicine**

PRADAXA

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**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.
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## 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)

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## Special population of interest

Other

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## Special population of interest, other

Non-valvular atrial fibrillation (NVAf) patients

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## Estimated number of subjects

500

## Study design details

## 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 items grouped 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 the following variables collected from patient medical records.

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## 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.

# Documents

## Study results

[1160-0280\\_c26547692-01.pdf](#)(243.69 KB)

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## Data management

## Data sources

## Data sources (types)

Other

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

### Data characterisation conducted

No