

Risk of major bleeding and associated health care resource utilization in non-valvular atrial fibrillation patients who initiated NOACs vs VKAs in the Hungarian population. A stratification on the propensity score method study.

**First published:** 08/08/2019

**Last updated:** 02/04/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS30879

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### Study ID

30880

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### DARWIN EU® study

No

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### Study countries

## Study description

The primary objective of the study is to give a descriptive analysis of the utilization of NOACs (apixaban, dabigatran, rivaroxaban) and VKAs (warfarin, acenocoumarol) in patients with NVAf in daily clinical practice on a large administrative database. The secondary objective of the study is to compare major bleeding rates and associated health care resource utilization between each NOAC and VKA users. A population based descriptive and stratification on the propensity score method, retrospective observational study using structured data from National Health Insurance Fund Administration database.

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## Study status

Planned

# Research institutions and networks

## Institutions

### Medical School Pécs

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

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Study contact

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**Primary lead investigator**

András Komócsi

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 05/07/2018

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**Study start date**

Planned: 01/10/2019

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**Data analysis start date**

Planned: 01/11/2019

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**Date of final study report**

Planned: 31/12/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer Hungary

# Study protocol

[Apixaban protocol final 27\\_JUN\\_2019 v2.0 15 jul.pdf](#) (1.22 MB)

## 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

## Other study registration identification numbers and links

Protocol number: X9001238

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

The primary objective of the study is to give a descriptive analysis of the utilization of NOACs (apixaban, dabigatran, rivaroxaban) and VKAs (warfarin, acenocoumarol) in patients with NVAf in daily clinical practice on a large administrative database. The secondary objective of the study is to compare major bleeding rates and associated health care resource utilization between each NOAC and VKA.

## Study drug and medical condition

**Medicinal product name**

ELIQUIS

XARELTO

PRADAXA

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**Medicinal product name, other**

Syncumar, Warfarin

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

APIXABAN

DABIGATRAN ETEXILATE

RIVAROXABAN

ACENOCOUMAROL

WARFARIN

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**Medical condition to be studied**

## Population studied

### 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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### Estimated number of subjects

10000

## Study design details

### Outcomes

Primary outcome measure will be: 1. safety outcome: major bleeding (intracranial, intraspinal, intraocular, pericardial, intra-articular, intramuscular with compartment syndrome, and retroperitoneal, bleeding that was fatal),

Secondary outcome measure will be: 1. effectiveness outcome:

ischemic/unspecified stroke, hemorrhagic stroke, or systemic embolism (SE), 2.

safety outcomes: myocardial infarction (MI), transfusion (CABG bleeding issue), (as individual endpoints).

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### Data analysis plan

All study variables, including baseline and outcome measures, will be analyzed descriptively and stratified by cohort. Crude incidence will be calculated as the number of events divided by person time. Pearson's chi-square tests will be

used to evaluate significant differences for dichotomous variables, Student's t-tests will be used for continuous variables.

## 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

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### Data sources (types), other

Hungary has a single payer insurance system, therefore, there is only one national database in the Hungarian health care system: the financial database of the National Health Insurance Fund. It includes all patients' data of state-funded services since 2000, those for pharmaceuticals, health spas and suppliers for patient transport. Any information for scientific research purposes can be obtained.

## 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