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

Study ID

30880

DARWIN EU® study

No

Study countries

Hungary

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.

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

Study start date
Planned: 01/10/2019

Data analysis start date
Planned: 01/11/2019

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

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

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

Medicinal product name, other
Syncumar, Warfarin

Study drug International non-proprietary name (INN) or common name
APIXABAN
DABIGATRAN ETEXILATE
RIVAROXABAN
ACENOCOUMAROL
WARFARIN

Medical condition to be studied

Atrial fibrillation

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)

Estimated number of subjects

10.000

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).

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No