

RIVA-DM: Effectiveness and Safety of Rivaroxaban vs. Warfarin in Nonvalvular Atrial Fibrillation and Diabetes Mellitus: Analysis of Electronic Health Record Data

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Study

Finalised

Administrative details

EU PAS number

EUPAS36634

Study ID

47671

DARWIN EU® study

No

Study countries

 United States

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/07/2020

Actual: 02/07/2020

Study start date

Planned: 21/08/2020

Actual: 21/08/2020

Data analysis start date

Planned: 31/07/2021

Actual: 31/07/2021

Date of final study report

Planned: 31/10/2021

Actual: 05/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

[21449_Study Protocol_V1.0_2020-08-19_Redacted.pdf](#) (679.75 KB)

[21449_Study Protocol_V2.0_2020-11-09_Redacted.pdf](#) (1.14 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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To compare the effectiveness and safety of rivaroxaban versus warfarin in NVAf patients with comorbid type 2 diabetes using the Optum® De-Identified EHR dataset, including: 1. The composite outcome of stroke or systemic embolism (SSE) 2. Any major or clinical-relevant nonmajor bleed resulting in hospitalization

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

RIVAROXABAN

WARFARIN

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

The study population of interest will be those with NVAF and comorbid type 2 diabetes, OAC-naïve and newly-initiated on rivaroxaban or warfarin (defined as the index date), be active in the data set for at least 12 months prior to the index event (based on the “First Month Active” field provided in the Optum data set) and have received care documented in the EHR database from at least one provider in the 12-months prior to the index date.

Selection criteria

To be included in the study patients will have to:

- Be ≥ 18 years of age at the time of anticoagulation initiation
- Have diagnoses of type 2 diabetes and NVAF (see Annex 1, .xlsx file for specific billing codes, code positions and encounter types)
- o Given the high specificity (>98%) of billing codes for identifying diabetes, a

code for diabetes will be considered sufficient to indicate diabetes in our study, regardless of A1c value (which is also a treatment goal)

o Due to the moderate sensitivity of billing codes for diabetes (~60-70%), patients without a billing code for diabetes, but having an A1c>6.5% AND receiving an antihyperglycemic medication (oral medications, GLP1-antagonists) will be considered diabetics as well

- Have no record of prior OAC use in the prior 12-months
- Newly initiated on rivaroxaban or warfarin
- Have ≥12-months of EHR activity prior to the index date and received care documented in the EHR database from at least one provider in the 12-months prior.

We will exclude patients with:

- Evidence of valvular heart disease defined as any rheumatic heart disease, mitral stenosis or mitral valve repair/replacement
 - Pregnancy
 - Use of rivaroxaban doses other than 15 mg once daily or 20 mg once daily or the presence of other indication(s) for OAC use
 - Any prior OAC utilization per written prescription or patient self-report at baseline.
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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)
-

Special population of interest

Other

Special population of interest, other

Nonvalvular Atrial Fibrillation patients

Estimated number of subjects

75000

Study design details

Outcomes

1. Composite of stroke or systemic embolism 2. Any major or clinical-relevant nonmajor bleed resulting in hospitalization, Secondary objectives will compare rivaroxaban versus warfarin in NVAF patients with comorbid type 2 diabetes for the risk of ischemic stroke, systemic embolism, need for revascularization or major amputation, intracranial hemorrhage, critical organ bleeding per ISTH categories, any extracranial bleeding, etc.

Data analysis plan

Patients receiving rivaroxaban will be 1:n matched to warfarin patients based on propensity scores. We will also use stabilized-inverse probability of treatment weighting (IPTW), overlap weighting and multivariable regression, competing risk regression approaches to adjust for potential confounding. Analysis of the primary effectiveness and safety endpoints by key subgroups will be performed as well.

Documents

Study results

Study report

[21449_Study Report_Redacted_V1.0_2021-11-05.pdf](#) (867.86 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)

[Administrative healthcare records \(e.g., claims\)](#)

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