Effectiveness and safety of rivaroxaban and amlodipine dual therapy compared to phenprocoumon and amlodipine dual therapy in non-valvular atrial fibrillation patients - using German health claims data

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Study Planned

Administrative details

EU PAS number

EUPAS105202

Study ID

105203

DARWIN EU® study

No

Study countries

☐ Germany

Study description

This is a retrospective cohort study of NVAF patients receiving a dual therapy of either rivaroxaban with amlodipine at specified doses or phenprocoumon with amlodipine in a real-world setting, where amlodipine is prescribed for the treatment of hypertension. The study focuses on effectiveness, safety outcomes, the drug utilization pattern, and patient characteristics for patients initiating treatment between years 2011 and 2019 using German claims data. The main objective of this study is to describe the effectiveness and safety associated with the use of rivaroxaban and amlodipine when compared to phenprocoumon and amlodipine. An analysis of relevant clinical and demographical data including subgroup analysis will be performed using a representative population from the German health claims data. The primary objective is to evaluate the effectiveness of rivaroxaban using a composite endpoint of prevention of ischemic stroke or systemic embolism. The safety of rivaroxaban and amlodipine will be assessed as a secondary objective based on the risk of bleeding at specific doses compared to dual therapy with phenprocoumon and amlodipine.

Study status

Planned

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ravi Iyer

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/10/2021

Actual: 15/11/2021

Study start date
Planned: 05/06/2023

Date of final study report
Planned: 29/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva Pharmaceutical, R&amp,D, Inc.

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To evaluate the effectiveness (composite endpoint: prevention of ischemic stroke and systemic embolism) of rivaroxaban and amlodipine at the specified doses – compared to the dual therapy of phenprocoumon and amlodipine where amlodipine is being used for the treatment of hypertension in patients with NVAF.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

AMLODIPINE

RIVAROXABAN

PHENPROCOUMON

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

4000

Study design details

Outcomes

Measuring the prevention of occurrence of the following events identified as hospitalisation for the composite endpoint of: • ischemic or undefined stroke /TIA, • systemic embolism (non?cerebrovascular embolism as retinal arterial occlusion, retinal vascular occlusion unspecified), The incidence rate of major bleeding as composite and single endpoints for the complete sample and

subgroups of interest

Data analysis plan

The average treatment effect of phenprocoumon/amlodipine users on the risk of ischemic stroke and systemic embolism compared to rivaroxaban/amlodipine will be obtained from time-to-event analysis using an application of the extended (weighted) Cox model. The observed hazard ratios (HR) between comparator cohorts will be provided with 95% CIs.

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