Non-interventional study on Edoxaban treatment in routine clinical practice for patients with non valvular atrial fibrillation (ETNA-AF-Europe)

First published: 19/05/2015

Last updated: 10/08/2017

Study Ongoing

Administrative details

EU PAS number

EUPAS8896

Study ID

20482

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Belgium
- ☐ France

- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Luxembourg
- [ ] Netherlands
- [ ] Portugal
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom

Study description

Edoxaban has recently been approved by the European Medicines Agency EMA for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, as well as for the treatment of adult patients with venous thromboembolism and the prevention of recurrent venous thromboembolism. In order to understand the risks and benefits of Edoxaban use in a real-world clinical setting, Daiichi-Sankyo proposed this post-authorization safety study (PASS) to gain insight into the safety (bleeding, liver adverse events, and other drug related adverse events) of Edoxaban use in non-preselected patients with non-valvular atrial fibrillation (NVAF).Real world evidence data of routine clinical practice use of Edoxaban up to 4 years will be collected in 13100 patients, treated by specialized as well as non-specialized physicians in hospitals and office based centres.

Study status

Ongoing

Research institutions and networks

Institutions

University of Birmingham

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Last updated: 01/02/2024

Institution

School of Clinical and Experimental Medicine

The total number of planned centres is 1500.

Europe

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Tessa Schliephacke

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/11/2014

Actual: 30/11/2014

Study start date
Planned: 01/08/2015

Actual: 14/08/2015

Data analysis start date
Planned: 01/10/2021

Date of interim report, if expected
Planned: 01/04/2019

Date of final study report
Planned: 31/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Daiichi Sankyo Europe GmbH

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Patient reported outcome

Main study objective:

The primary objective of this study is to collect real-world safety data on bleeding events, drug related adverse events in AF patients treated with Edoxaban up to 4 years. Furthermore, subgroup analyses will be performed in predefined patient populations, such as patients with renal or hepatic impairment.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional post-authorisation safety study

Study drug and medical condition

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

EDOXABAN TOSYLATE

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)

Special population of interest

Renal impaired

Hepatic impaired

Estimated number of subjects

13100

Study design details

Outcomes

Major bleeding events including intracranial haemorrhage, fatal bleeding events, clinically relevant non-major bleeding events, stroke, systemic embolic events, cardiovascular (CV) events leading to hospitalisation, CV mortality, all-cause mortalitySuspected Edoxaban related adverse events, To assess the effect of Edoxaban on patient relevant outcomes as strokes, systemic embolic events, major cardiovascular events, hospitalisations related to cardiovascular condition, persistence to therapy, patient/physician reported outcome, health care utilization and resource use

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Data analysis plan

Details of the data analysis strategy will be fully described in a Statistical Analysis Plan (SAP). Briefly, all collected variables will be used in the statistical analysis. Binary, categorical, and ordinal parameters will be summarised by means of absolute and percentage numbers within the various categories. Numerical data will be summarised by means of standard statistics. In addition, adequate graphs (eg bar charts, box-whisker plots) may be presented. Kaplan-Meier plots will be generated where applicable to characterize the risk over time for each outcome. The purpose of all analyses will not be confirmatory but purely descriptive/exploratory.

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)

Non-interventional study

Other

Data sources (types), other

Prospective patient-based data collection

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