Non-interventional study on Edoxaban treatment in routine clinical practice in patients with venous thromboembolism

First published: 26/09/2016

Last updated: 06/03/2017

Study Ongoing

Administrative details

EU PAS number

EUPAS15504

Study ID

18098

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Germany
- Ireland

Italy

Netherlands

Switzerland

United Kingdom

Study description

Edoxaban is an orally administered anticoagulant that inhibits coagulation factor Xa. It has been recently approved by the European Medical Agency (EMA) for use in adult patients for the treatment of acute venous thromboembolism (VTE) including deep vein thrombosis (DVT) and/or pulmonary embolism (PE), and prevention of recurrent VTE in adults. According to current guidelines, duration of anticoagulant treatment after a venous thromboembolic event varies from 3 months to indefinite treatment depending on the estimated risks of venous thromboembolism (VTE) recurrence and bleeding. Current data for edoxaban are limited to a maximum treatment duration of 12 months (Hokusai-VTE, N Engl J Med. 2013, 369:1406-15). Therefore, this study aims to gather further insight into efficacy (i.e. symptomatic recurrent VTE) and safety (i.e. bleeding events, liver adverse events, all-cause mortality and other drug related adverse events) of extended treatment with edoxaban up to 18 months in an unselected patient population in routine clinical practice.

Study status

Ongoing

Research institutions and networks

Institutions

Guy's and St Thomas' NHS Foundation Trust

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Primary lead investigator

Alexander Cohen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/12/2014

Study start date

Planned: 01/02/2017

Actual: 22/12/2016

Data analysis start date

Planned: 01/02/2021

Date of final study report
Planned: 15/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Daiichi-Sankyo-Europe

Study protocol

ETNA-VTE-Europe_Obsplan_version 04_final signed.pdf (2.41 MB)

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)

Main study objective:

Primary objective is the analysis of the overall symptomatic VTE recurrence rate during an overall observational period of 18 months in unselected patients with acute VTE. The co-primary objective of this study is to collect and evaluate real-world safety data on bleeding events, drug related adverse events such as liver adverse events, and mortality (VTE-related, CV mortality, and all-cause

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

Venous thrombosis

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

2.700

Study design details

Outcomes

Symptomatic VTE recurrence rate during an overall observational period of 18 months in unselected patients with acute VTE, symptomatic VTE recurrence rate for patients on edoxaban, the symptomatic VTE recurrence rate for patients who discontinued edoxaban, patient relevant outcomes such as strokes (ischaemic and haemorrhagic), systemic embolic events (SEE), hospitalisations related to CV condition (including VTE related hospitalisation), post-thrombotic Syndrom, compliance

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Data analysis plan

Binary, categorical, and ordinal parameters will be summarised by means of absolute and relative (percentage) frequencies within the various categories. Continuous parameters will be summarised by means of standard descriptive

summary statistics. In addition, adequate graphs (e.g. bar charts, box-whisker plots) will be presented. Kaplan-Meier plots will be generated where ap

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

Prospective patient-based data collection, Exposure registry

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