European bivalirudin utilisation in practice 2 (EUROVISION 2)

First published: 30/07/2014

Last updated: 25/06/2025

Study Finalised

Administrative details

EU PAS number

EUPAS7143

Study ID

30897

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece

- [ ] Netherlands
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

The Medicines Company was requested by the European Medicines Agency (EMA) to conduct a drug utilization study. This simple survey was designed to collect brief data for the last 10 consecutive patients who underwent a PCI and were treated with Angiox at a randomly selected number of institutions. Institutions were asked to fill in a short online questionnaire relating to the use of Angiox. Information for this survey was collected from patient medical records while maintaining patients' anonymity. There was no source data verification at institutions. The EU marketing authorisation for Angiox has now been withdrawn, with effective date 1 July 2018. The marketing authorisation was withdrawn for commercial reasons and not due to any safety, efficacy, quality or compliance concerns.

Study status

Finalised

Research institutions and networks

Institutions

THE MEDICINES COMPANY (Schweiz) GmbH

Multiple centres: 25 centres are involved in the study

Contact details

Study institution contact

Scott Johnson Medical.Information@THEMEDCO.com

Study contact

Medical.Information@THEMEDCO.com

Primary lead investigator

David Sampson

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2014

Actual: 01/07/2014

Study start date

Planned: 03/11/2014

Actual: 23/10/2014

Data analysis start date

Planned: 04/01/2016

Actual: 04/01/2016

Date of final study report

Planned: 31/03/2016

Actual: 31/03/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

The Medicines

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

Drug utilisation study

Study drug and medical condition

Medicinal product name

ANGIOX

Medical condition to be studied

Percutaneous coronary intervention

Population studied

Short description of the study population

Last 10 consecutive patients who underwent a percutaneous coronary infusion (PCI) and were treated with Angiox at a randomly selected number of institutions.

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

267

Study design details

Data analysis plan

Descriptive statistics and/or patient data listings will be used to summarise the data.Continuous variables will be summarised by means, standard deviations, medians, inter-quartile ranges, and minimum and maximum values. Categorical variables will be summarised by frequencies and percentages.

Documents

Study results

EUROVISION 2 Results Final.pdf (94.81 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)

Other

Data sources (types), other

Patients' medical records

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