# European bivalirudin utilisation in practice 2 (EUROVISION 2)

First published: 30/07/2014

**Last updated:** 25/06/2025





# Administrative details

EU PAS number	
EUPAS7143	
Study ID	
30897	
<b>DARWIN EU® study</b> No	
Study countries  Austria	
Belgium	
Finland	
France	
Germany	
Greece	

etherlands
pain
weden
nited 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 The EU marketing authorisation for Angiox has now been withdrawn, with effective date 1 July 2018. The marketing authorisation was withdrawn for commercial reasons and not due to any safety, efficacy, quality or compliance concerns.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

#### Name of medicine

**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