# Studies on the impact of vasoconstrictors on the risk of myocardial infarction and stroke (PGRx-VASO)

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## Administrative details

#### **EU PAS number**

EUPAS10239

#### Study ID

22729

#### **DARWIN EU® study**

No

#### **Study countries**

France

### **Study description**

The main assessment criterion that served for the study power estimation is to determine whether exposure to vasoconstrictors is associated with an increased risk of occurrence of stroke and / or of myocardial infarction (MI). The endpoint is composite: - Haemorrhagic or ischemic Stroke - Myocardial infarction (MI) Other objectives are to determine if exposure to vasoconstrictors is associated with an increased risk of occurrence of MI and to determine whether exposure to vasoconstrictors is associated with an increased risk of occurrence of haemorrhagic or ischemic stroke. The study design is a case-crossover study of patients with MI or stroke. The case-crossover analysis will compare drug exposure between a risk-time-period and a reference-time-period within the same patient.Population is recruited all over France (PGRx system) that has shown good representativity of patients with myocardial infarction or stroke.Medical information is entered by cardiologists and neurovascular specialists in the PGRx system. Drug exposure is obtained from cardiologists and neurovascular specialists, and patients through standardized and validated telephone interviews. A total of 2700 patients with MI or stroke (1350 each) will be needed to achieve a power of 80% to detect an Odds ratio between 1.51 and 1.76 depending on the VC utilisation on the reference period (1 or 2 % respectively), for the comparison of VCs to no VC use.

#### **Study status**

Finalised

## Research institutions and networks

## Institutions

## Real World Studies, LA-SER Research

France

United Kingdom

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## Networks



# Contact details

### Study institution contact

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Primary lead investigator

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Primary lead investigator

# Study timelines

**Date when funding contract was signed** Planned: 20/12/2013 Actual: 20/12/2013

**Study start date** Planned: 01/10/2013 Actual: 01/10/2013

Data analysis start date Planned: 01/12/2015 Actual: 06/07/2016

Date of final study report Planned: 01/02/2016 Actual: 28/10/2016

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Severals

Regulatory

### Was the study required by a regulatory body?

Yes

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

Not applicable

## Methodological aspects

# Study type

# Study type list

### Study topic:

Human medicinal product

### Study type:

Non-interventional study

### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

### Data collection methods:

Combined primary data collection and secondary use of data

### Main study objective:

The main objective of the study is to determine whether exposure to vasoconstrictors is associated with an increased risk of occurrence of stroke and/or of myocardial infarction. The endpoint is composite: - Haemorrhagic or

# Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-crossover

# Study drug and medical condition

### Anatomical Therapeutic Chemical (ATC) code

(R01A) DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

# **Population studied**

### Short description of the study population

For MI cases: Patients who have first diagnosed MI (incident cases) within 45 days prior to inclusion, diagnosis made by board-certified cardiologists. For stroke cases: Patients who have first haemorrhagic or ischemic stroke within 45 days prior to inclusion, documented by CT scan or MRI, and diagnosis made by a specialist (neurologist, cardiologist, internal medicine physician).

#### Age groups

Adults (18 to < 46 years)

### Estimated number of subjects

2700

# Study design details

#### Outcomes

The endpoint is composite: - Haemorrhagic or ischemic Stroke - Myocardial infarction, Other objectives:- To determine if exposure to vasoconstrictors is associated with an increased risk of occurrence of myocardial infarction- To determine whether exposure to vasoconstrictors is associated with an increased risk of occurrence of haemorrhagic or ischemic stroke

### Data analysis plan

The analytic plan will proceed through:- Description of patients and participation rates- Description of cases of MI and stroke- Description of nonparticipants (including dead patients)- Description of risk factors and comorbidities in cases of MI and stroke - Description of vasoconstrictors (VCs) use-Description of time varying risk factors variables- Unadjusted comparison of VCs use and no VCs use in risk and referent time windows in cases - Adjusted comparison of VCs use and no VCs use in risk and referent time windows in cases- Collinearity analysis- Sensitivity analysisA sample size of 2700 patients (1350 MI, 1350 stroke) has been retained under the hypothesis of a detectable odds ratio (between 1.51 and 1.76) with 95% confidence and 80% power in different assumptions of exposure in the reference period (1 or 2% respectively).The statistical analytical plan is developed and approved by the scientific committee.

## Documents

## 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 source(s), other** PGRx-ACS database, PGRx-Stroke database

#### Data sources (types)

Other

#### Data sources (types), other

Case-crossover study design using observational PGRx system.Eligible incident cases of stroke and MI are selected from ACS & Stroke cases registries identified prospectively at the time of occurrence of the ACS/Stroke.Incident MI and stroke are respectively recruited by cardiologists and neurologists PGRx networks.

# 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

Unknown