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

First published: 22/07/2015

Last updated: 31/03/2024

Study | Finalised

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

First published: 23/03/2012

Last updated: 23/03/2012

Institution | Outdated | Other | ENCePP partner

Networks

PGRx®

France

United Kingdom

First published: 30/03/2010

Last updated: 17/01/2012

Network | Outdated | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Lamiae Grimaldi

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

ischemic Stroke - Myocardial infarction

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
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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)

- Adults (46 to < 65 years)

Estimated number of subjects

2.700

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

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Data analysis plan

The analytic plan will proceed through:- Description of patients and participation rates- Description of cases of MI and stroke- Description of non-participants (including dead patients)- Description of risk factors and co-morbidities 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

Study results

PGRxVASO_Executive_Summary_Posted_ENCePP.pdf (625.76 KB)

Data management

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