Stroke Prevention and anticoagulants (SPA)

First published: 11/05/2015

Last updated: 22/02/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17585

EU PAS number

EUPAS9374

Study ID

17585

DARWIN EU® study

No

Study countries

☐ France

Study description

The primary objective of this study is to assess the relative risk of stroke (ischaemic or haemorrhagic stroke) in patients with atrial fibrillation using dabigatran and in those using other new oral anticoagulant therapies (rivaroxaban, apixaban) as compared to the use of any vitamin K antagonist (VKA: fluindione, acenocoumarol or warfarin), For clarity, an odds ratio will be estimated for dabigatran vs. VKA (any), for rivaroxaban vs. VKA (any) and for apixaban vs. VKA. The study is powered for the assessment of dabigatran use vs. VKA (any) use.Secondary objectives:• To describe the patterns of use of dabigatran and other anticoagulant therapies in non-valvular atrial fibrillation• To assess the risk of haemorrhage in patients participating in the study treated with anticoagulants (dabigatran, rivaroxaban, apixaban, VKA) • To assess what risk factors influence the risk of stroke in patients with and without the different anticoagulant therapiesThe study design is a systematic case-referentThe sample size of 2.650 cases and 5.300 controls is estimated as necessary to detect an odds ratio of 0.80 with 95% confidence and 80% power assuming that 20% of referents (patients with atrial fibrillation and no stroke) will be exposed to dabigatran on average during the study period

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Study status

Ongoing

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 | Other | ENCePP partner

Networks

PGRx®

France

United Kingdom

First published: 30/03/2010

Last updated: 17/01/2012

Network | 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
Actual: 20/12/2012

Study start date
Actual: 05/12/2013

Data analysis start date
Planned: 02/11/2016

Date of final study report
Planned: 24/01/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

SPA_Executive summary of protocol.pdf(138.48 KB)

SPA_Executive summary of protocol_20160129.pdf(630.4 KB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To assess the relative risk of stroke (ischaemic or haemorrhagic stroke) in patients with atrial fibrillation using dabigatran and in those using other new oral anticoagulant therapies (rivaroxaban, apixaban) as compared to the use of any vitamin K antagonist (VKA: fluindione, acenocoumarol or warfarin)

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AE) Direct thrombin inhibitors

Direct thrombin inhibitors

Medical condition to be studied

Ischaemic stroke

Haemorrhagic stroke

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)

Estimated number of subjects

7950

Study design details

Outcomes

stroke (ischaemic or haemorrhagic stroke), Haemorrhage (major, leading to hospitalisation), or non-major i.e moderate (visit to a physician or emergency room and/or treatment required) or minor (others)

Data analysis plan

For the main analysis, conditional logistic regression will be used in order to be consistent with case-control matching. The model will include recent exposure to anticoagulant therapy (see below), past exposure to anticoagulant therapy including past switches or discontinuation in anticoagulant therapy, as well as risk factors for stroke, i.e. both a priori selected risk factors and a posteriori selected risk factors based on their association with stroke.

Data management

ENCePP Seal

Composition of steering group and observers

SPA_Comité_Scientifique.pdf(169.2 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Case-control surveillance database

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