Stroke Prevention and anticoagulants (SPA)

First published: 11/05/2015

Last updated: 22/02/2024





Administrative details

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 therapies The study design is a systematic case-referent The 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

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Institution Outdated Other ENCePP partner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Network Outdated ENCePP partner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

Lamiae Grimaldi lamiae.grimaldi@la-ser.com

Study contact

lamiae.grimaldi@la-ser.com

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:

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

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.

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