# Stroke Prevention and anticoagulants (SPA)

**First published:** 11/05/2015

**Last updated:** 22/02/2024

Study Ongoing

## 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 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

**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Institution | Outdated | Other | ENCePP partner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Network | Outdated | ENCePP partner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**

7.950

## 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