

# Riesgo de accidente vascular cerebral asociado al uso de medicamentos: estudio de casos y controles (IJG-AVC-2015)

**First published:** 09/03/2016

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS12733

### Study ID

13012

### DARWIN EU® study

No

### Study countries

☐ Spain

### Study status

Ongoing

## Research institutions and networks

## Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

☐ Spain

**First published:** 05/10/2012

**Last updated:** 23/05/2025

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**Not-for-profit**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[aquijada@idiapjgol.org](mailto:aquijada@idiapjgol.org)

### Primary lead investigator

Maria Angeles Quijada Manuitt

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 02/11/2015

Actual: 15/01/2016

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**Study start date**

Planned: 14/03/2016

Actual: 14/03/2016

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**Date of final study report**

Planned: 31/01/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Beribérica S.A.

## Study protocol

[Protocolo ICTUS v01 23-12.pdf](#)(659.06 KB)

[Protocolo ICTUS v02 01-04.pdf](#)(659.09 KB)

## Regulatory

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

No

## Methodological aspects

## Study type

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Main study objective:**

To assess the association between stroke and exposure to different pharmacological groups and active principles

## Study Design

**Non-interventional study design**

Case-control

## Study drug and medical condition

**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)

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### **Estimated number of subjects**

132000

## Study design details

### **Outcomes**

Demographic and anthropometric characteristics (age, sex, geographic distribution, MEDEA index, physical activity and BMI), toxic habits (smoking, alcohol), medical history (hypertension, diabetes, cardiovascular, cerebrovascular and peripheral vascular disease, osteoarthritis, inflammatory arthritis, dementia, bipolar disorder, depression/anxiety, chronic obstructive pulmonary disease, etc.), Charlson index, frequenting primary care (number of visits in the last year) and the number of prescriptions (active on index date), laboratory parameters (lipid profile, glycaemia and glycated hemoglobin, uric acid, glomerular filtration rate last predetermination to the index date), cardiovascular risk assessment and drug exposure.

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### **Data analysis plan**

We will analyze stroke risk associated with exposure to drugs adjusted by risk factors (age, sex, and other variable tha are shown associated with the disease and possibly the exhibition of the population) by logistic regression .We plan to conduct a subanalysis in populations with osteoarthritis and dementia.Associations will be expressed as odds ratio estimates and confidence intervals of 95%.

## 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)

The Information System for Research in Primary Care (SIDIAP)

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No