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

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/13012

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

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Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **Not-for-profit** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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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

Study start date
Planned: 14/03/2016

Actual: 14/03/2016

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 list

Study type:

Non-interventional study

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)

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.

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

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Data sources (types)

Electronic healthcare records (EHR)

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