

# Use of antidepressant drugs and its association with risk of stroke, frequency of hospitalization, and mortality in an elderly population: a descriptive and analytic cohort study

**First published:** 01/06/2017

**Last updated:** 01/06/2017

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS19188

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### Study ID

19189

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### DARWIN EU® study

No

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### Study countries

 Spain

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## **Study description**

This is an observational study which will describe the use of antidepressants in an elderly population and assess its association with stroke, hospitalizations due to stroke and death in an elderly population during 2009-2015. A retrospective descriptive drug utilization study in a population aged over 65 and registered in the System for the Development of Research in Primary Care database (SIDIAP). Demographic and clinical patient characteristics, selected co-morbidities, clinical indications of antidepressant use, prescribed active ingredient of antidepressant, selected co-medications, prescribed dose and duration of antidepressants, switchers and discontinuers will be described. Prevalence of antidepressant use and rate of switchers and discontinuers will be measured. A retrospective study with matched cohorts will be conducted in a population aged over 65 and registered in the System for the Development of Research in Primary Care database (SIDIAP). Cases are incident users of antidepressant medication (tricyclic antidepressants, selective serotonin reuptake inhibitors, and other antidepressants), controls will not have used this type of medication. The research will evaluate the association of new prescription of antidepressants for any indication and occurrence of first episode of stroke, hospitalization or death. The information will be obtained from SIDIAP database (which has information of 5.8 million primary care patients from Institut Català de la Salut), DATAMART® database (Pharmaceutical dispensation information from Catalan Health Service) and CMBD database (Hospital discharge registry from General Hospital of National Health System).

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## **Study status**

Ongoing

## **Research institutions and networks**

### **Institutions**

# Fundació Institut Català de Farmacologia (FICF)

 Spain

**First published:** 29/03/2010

**Last updated:** 17/09/2019

**Institution**

**Outdated**

**Educational Institution**

**Hospital/Clinic/Other health care facility**

**Not-for-profit**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[li@icf.uab.cat](mailto:li@icf.uab.cat)

### Primary lead investigator

Luisa Ibañez

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 14/07/2015

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### Study start date

Planned: 01/06/2016

Actual: 13/09/2016

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### **Date of final study report**

Planned: 31/12/2018

## Sources of funding

- EU institutional research programme
- Other

## More details on funding

Instituto de Salud Carlos III, European Regional Development Fund (FEDER))

## Study protocol

[Protocol-EUPAS19188-20170601.pdf](#) (779.26 KB)

## Regulatory

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

No

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

Drug U: To describe the incident use of antidepressant drugs in a population  $\geq 65$  years old during the period of 2009-2015. Risk A: To compare time to occurrence of the composite outcome variable: first episode of nonfatal stroke, fatal stroke, hospitalization due to stroke, or death from any cause among elderly new users and nonusers of SSRI antidepressant drugs

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(N06AA) Non-selective monoamine reuptake inhibitors

Non-selective monoamine reuptake inhibitors

(N06AB) Selective serotonin reuptake inhibitors

Selective serotonin reuptake inhibitors

(N06AX) Other antidepressants

Other antidepressants

(N06CA) Antidepressants in combination with psycholeptics

Antidepressants in combination with psycholeptics

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### **Medical condition to be studied**

Death

Haemorrhagic stroke

Ischaemic stroke

Cerebellar stroke

Hospitalisation

## Population studied

### **Age groups**

- Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Estimated number of subjects**

417685

## Study design details

### **Outcomes**

Risk A: Composite variable of fatal or nonfatal stroke, hospitalization due to stroke, or death from any cause, Risk A: Every single event of the composite outcome

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### **Data analysis plan**

Drug U: Demographic, diagnostic and pharmacoepidemiologic data will be analysed using descriptive statistics. Prevalence of antidepressant use will be described for all the study period (2009-2015), and for each year stratified by age group, sex, and indication of prescription. Variables will be reported as mean  $\pm$  standard deviation, median or as frequency and percentage, as appropriate. Risk A: The cohorts will be formed by matching on the propensity score (PS) of their baseline characteristics. PS will be calculated by logistic regression of antidepressant use. Crude incidence rates, rate ratios and adjusted incidence rates and rate ratios will be reported for the composite outcome. For reporting adjusted incidence rates, calculated by Poisson regression will be used. The hazard ratio for the risk of composite outcome will be calculated. An analysis of marginal structural models for co-morbidity and other confounding variables, whose exposure varies over time, will be applied.

## 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.

### **Signed checklist for study protocols**

[EUPAS19188-19381.pdf](#) (155.41 KB)

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### Data sources

**Data source(s)**

The Information System for Research in Primary Care (SIDIAP)

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**Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

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

[Other](#)

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**Data sources (types), other**

Hospital Discharge Records linked with the database from SIDIAP

## 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