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

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Study Ongoing

Administrative details

EU PAS number

EUPAS19188

Study ID

19189

DARWIN EU® study

No

Study countries

Spain

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 Intitut 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).

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Institution | Outdated | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner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

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Primary lead investigator

Luisa Ibañez

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/07/2015

Study start date

Planned: 01/06/2016

Actual: 13/09/2016

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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 ≥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

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)

Estimated number of subjects

417.685

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 ± 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)

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No