ANGIOtensin Agents and Reduction of AntiDEPRESSANT Drugs' Prescription (ANGIODEPRESSANTS): A Cohort Study Using Real-World Data.

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46105

EU PAS number

EUPAS43831

Study ID

46105

DARWIN EU® study

No

Study countries

Spain

Study description

A retrospective cohort study will be performed by analyzing data obtained from the Catalan Southern Metropolitan data warehouse system, which collects data from both hospitalized and primary care patients from the Bellvitge University Hospital's area of influence. The investigators will begin by gathering information only on patients treated with antihypertensive drugs, which then will be stratified in two groups: 1) Angiotensin Agents group, 2) Other Antihypertensive Agents (Non-Angiotensin Agents) group. Afterwards, a separated analysis will be performed to assess the effects of ARBs and ACEIs separately on the prescription of antidepressant drugs.

Study status

Planned

Research institutions and networks

Institutions

Bellvitge University Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sebastià Videla

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/02/2020

Study start date
Planned: 03/04/2022

Date of final study report
Planned: 30/10/2022

Sources of funding

- Other

More details on funding

Investigators own resources

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

ClinicalTrials.gov: NCT04899206

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Main study objective:

Our primary objective is to estimate the prevalence, incidence, and clearance (incidence of antidepressant drugs withdrawal) of antidepressant drugs prescription in hypertensive patients under treatment with angiotensin agents

(ARBs and/or ACEIs).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Hypertension

Depression

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

15000

Study design details

Outcomes

Primary Outcome Measures: • Number of patients under treatment with antihypertensive drugs and with antidepressant drugs • Number of patients under treatment with antihypertensive drugs, Secondary Outcome Measures: 1. Number of patients diagnosed with Hypertension 2. Number of patients diagnosed with Depression 3. Number of patients treated with ARBs 4. Number of patients treated with ACEIs 5. Number of patients treated with other antihypertensive drugs 6. Number of patients treated with Amitriptyline 7. Number of patients treated with Duloxetin

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Data analysis plan

A general descriptive analysis of all study variables will be provided. The results will be expressed as means and standard deviation, the median (maximum and minimum values) for the quantitative variables, and the absolute and relative frequencies of each category, for the categorical variables. The prevalence and incidence and their 95% confidence intervals will be estimated. The ‘time until beginning’ and the ‘time until withdrawal’ of an antidepressant drug will be calculated. An exploratory analysis by gender will be carried out. The software used to perform the statistical analysis will be R version 3.6 or higher.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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