Utilization of antidementia treatments: a large multinational-network population-based study.

First published: 04/04/2023

Last updated: 23/04/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/104350

EU PAS number

EUPAS104349

Study ID

104350

DARWIN EU® study

No

Study countries

☐ Netherlands

United Kingdom

Study description

We aim to characterize and analyse the use of antidementia drugs in three different countries, through a multinational network cohort study that will gather information from real-world health care databases: Sistema d'Informació per al Desenvolupament de la Atenció Primària (SIDIAP), Health Informatic Center (HIC), Clinical Practice Research Datalink (CPRD) and the Integrated Primary Care Information (IPCI), standardized to the Common Data Model OMOP. Inclusion criteria: we will include individuals with at least 40 years or older with dementia, registered for at least 1 year before cohort entry and with at least 1 prescription of rivastigmine, galantamine, donepezil or memantine during the study period. Outcomes: demographics, comorbidities, prescriber-type, prescribing pattern and proportion of 'prescription cascade' drugs (prescriptions generated to alleviate adverse events). Statistics: Yearly age-sex incidence rates (IR) and Kaplan Meier curves to assess the duration and drug discontinuation.

Study status

Planned

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: 23/02/2024

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

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

IPCI The Netherlands, HIC Scotland (UK)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Carlen Reyes

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2022

Study start date

Planned: 01/01/2023

Date of final study report

Planned: 30/11/2023

Sources of funding

- Other

More details on funding

IDIAPJGol, University of Oxford

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:

Drug utilisation

Main study objective:

The aim of the present project is to characterize and assess the drug use of patients with dementia and the prescription of antidementia drugs (rivastigmine, galantamine, donepezil and memantine) in real-world data.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06DA) Anticholinesterases

Anticholinesterases

(N06DX01) memantine

memantine

Medical condition to be studied

Dementia

Population studied

Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

81502

Study design details

Data analysis plan

Statistics: Yearly age-sex incidence rates (IR) and Kaplan Meier curves to assess the duration and drug discontinuation.

Data management

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

Clinical Practice Research Datalink

Data source(s), other

HIC United Kingdom

Data sources (types)

Administrative healthcare records (e.g., claims)

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