DARWIN EU® - Antipsychotic prescribing in people with dementia in Europe: a descriptive analysis of trends and patient characteristics

First published: 09/12/2024

Last updated: 02/01/2025

Study   Ongoing

Administrative details

EU PAS number

EUPAS1000000382

Study ID

1000000382

DARWIN EU® study

Yes

Study countries

☐ Belgium

☐ Croatia

☐ Denmark

- ☐ Germany
- ☐ Netherlands
- ☐ Spain

Study description

Antipsychotic drugs have been associated with several adverse drug reactions, particularly in the elderly. Somnolence, hypotension, extrapyramidal side effects and gait abnormalities are well-recognised side effects that may in turn contribute to the risk of falls and fracture in elderly persons. Similarly, cardiovascular adverse effects, falls and injuries may increase mortality. Antipsychotic drugs are indicated for the management of schizophrenia and bipolar disorder. Antipsychotics are also used to manage behavioral and psychological symptoms of dementia (BPSD) and recommendations over their use suggest they should be discontinued after BPSD symptoms resolve. Safety concerns have previously led to regulatory warnings and risk communications over their use.

Antipsychotic drugs can be classified into typical and atypical antipsychotics with different recommendations for their use. For example, guidelines recommend the preferential use of atypical antipsychotics when required for the management of BPSD.

The rationale of the study is to provide an overview of common antipsychotic prescribing in Europe, and to describe the characteristics of patients initiating antipsychotics. This may help to contextualize information contained in future antipsychotic periodic safety update reports.

Study status

Ongoing

Research institutions and networks

Institutions

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

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

☐ Belgium

☐ Croatia

☐ Denmark

☐ Estonia

☐ Finland

☐ France

☐ Germany

☐ Greece

☐ Hungary

☐ Italy

☐ Netherlands

☐ Norway

☐ Portugal

☐ Spain

☐ Sweden

☐ United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marta Pineda Moncusi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/07/2024

Actual: 09/07/2024

Study start date

Planned: 09/07/2024

Actual: 09/07/2024

Date of final study report

Planned: 31/01/2025

Sources of funding

- EMA

Study protocol

Protocol_P3-C1-013_Antipsychotics dementia_V2.pdf(726.91 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

- New user cohort study (Objective 1 and 4, Patient-level antipsychotic utilisation)
- Population level cohort study (Objective 2, Population-level antipsychotic drug utilisation)
- New user cohort study (Objective 3, Patient-level characterisation)

Main study objective:

1. To characterise people with dementia (overall, vascular dementia and Alzheimer's disease) with a first use of common antipsychotics in terms of age, gender, comorbidities, and indication

2. To measure trends in the incidence of first use of common antipsychotic prescribing among people with dementia (overall, vascular dementia and Alzheimer's disease) overall, by typical/atypical grouping and by the top 20 most commonly prescribed drug substances. Results will be stratified by database, calendar year, age and sex.

3. To characterise first time users of common antipsychotic drug therapy in people with dementia (overall, vascular dementia and Alzheimer's disease) by

drug substance (in terms of dose and duration). Results will be stratified by drug route, age and sex.

4. To measure overall survival in people with dementia (overall, vascular dementia and Alzheimer's disease) with a first use of common antipsychotic overall, for typical/atypical grouping and for the top 20 most common drug substances.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Common antipsychotics (ATC: N05A)

Substances included:

• Sulpiride

• Quetiapine

• Risperidone

• Olanzapine

• Haloperidol

• Aripiprazole

• Piamperone

• Prothipendyl

• Prochlorperazine

• Chlorprothixene

• Promazine

- Paliperidone

- Zuclopenthixol

- Clozapine

- Fluspirilene

- Amisulpride

- Fluphenazine

- Perphenazine

- Pimozide

- Ziprasidone

Anatomical Therapeutic Chemical (ATC) code

(N05A) ANTIPSYCHOTICS

ANTIPSYCHOTICS

Medical condition to be studied

Dementia

Population studied

Short description of the study population

The study cohort will comprise all individuals on 1st of January of each year in the period 2013-2023 (or the latest available), with at least 365 days of data availability before the day they become eligible for study inclusion and a prior diagnosis of dementia.

Data management

Data sources

Data source(s)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

Integrated Primary Care Information (IPCI)

Danish Health Data Registries

The Information System for Research in Primary Care (SIDIAP)

IQVIA Disease Analyzer Germany

IQVIA Longitudinal Patient Data - Belgium

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown