DARWIN EU® - Antipsychotic prescribing in the general population in Europe: a descriptive analysis of trends and patient characteristics

First published: 04/10/2024

Last updated: 07/03/2025

Study   Finalised

Administrative details

EU PAS number

EUPAS1000000330

Study ID

1000000330

DARWIN EU® study

Yes

Study countries

☐ Belgium

☐ Croatia

☐ Denmark

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.

Study status

Finalised

Research institutions and networks

Institutions

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

☐ United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution   Educational Institution   Hospital/Clinic/Other health care facility

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

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/07/2024

Actual: 09/07/2024

Study start date

Planned: 18/09/2024

Actual: 18/09/2024

Date of final study report

Planned: 07/02/2025

Actual: 08/01/2025

Sources of funding

- EMA

Study protocol

[DARWIN EU_Protocol_P3-C1-012_Antipsychotic in general population_V4.pdf](#)

(745.39 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:

Retrospective cohort studies will be conducted using routinely collected health data from 6 databases.

Main study objective:

1. To characterise people with dementia (overall, vascular dementia and Alzheimer's disease) with first

use of common antipsychotics in terms of age, gender, indication, comorbidities.

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 top 20 most common drug substances. Results will be stratified by database, calendar year, age and

sex.

3. To characterise first time users of common antipsychotic drug therapy after initiation in people with

dementia (overall, vascular dementia and Alzheimer's disease) by drug substance (in terms of initial

dose and duration).

4. To measure overall survival in people with dementia (overall, vascular dementia and Alzheimer's

disease) with first use of common antipsychotic overall, for typical/atypical grouping and for top 20

most common drug substances.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, 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

Study drug International non-proprietary name (INN) or common name

ARIPIPRAZOLE

OLANZAPINE

PALIPERIDONE

RISPERIDONE

Anatomical Therapeutic Chemical (ATC) code

(N05A) ANTIPSYCHOTICS

ANTIPSYCHOTICS

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. Additional eligibility criteria will be applied for the identification of new users:

1. When overall, no prior use of any of the common antipsychotics will be

required. In other words, users with prior use of any of the antipsychotics of interest will be excluded from the analysis.

2. When stratified by specific antipsychotic drug, no prior use of the specific antipsychotic will be required. In other words, users with prior use of the same antipsychotic will be excluded from the analysis.

Study design details

Setting

This study will be conducted using routinely collected data from 6 databases from 6 European countries. All databases were previously mapped to the OMOP CDM.

1. SIDIAP (Spain, Primary Care Database) [Objective 1 to 4]
2. IPCI (Netherlands, Primary Care Database) [Objective 1 to 4]
3. DK-DHR (Denmark, National Registry) [Objective 1 to 4]
4. IQVIA DA Germany (Primary Care database) [Objective 1 to 3]
5. IQVIA LPD Belgium (Primary Care database) [Objective 1 to 3]
6. NAJS (Croatia, National Registry) [Objective 1 and 2]

Documents

Study report

DARWIN EU_Report_P3-C1-012_Antipsychotics general population_V3.pdf (2.53 MB)

Data management

ENCePP Seal

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

Danish Health Data Registries

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

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