

# 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

 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.

---


## **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

Ilse Schuemie [study@darwin-eu.org](mailto:study@darwin-eu.org)

Study contact

[study@darwin-eu.org](mailto:study@darwin-eu.org)

### 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: 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
- Pimiperone
- Prothipendyl
- Prochlorperazine

- Chlorprothixene
  - Promazine
  - Paliperidone
  - Zuclopenthixol
  - Clozapine
  - Fluspirilene
  - Amisulpride
  - Fluphenazine
  - Perphenazine
  - Pimozide
  - Ziprasidone
- 

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

ARIPRAZOLE

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

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.

## 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