DARWIN EU® Rates of occurrence of treatment-related intercurrent events in patients with major depressive disorder

First published: 03/10/2023

Last updated: 14/08/2026

Study Finalised

Administrative details

EU PAS number

EUPAS106685

Study ID

107562

DARWIN EU® study

Yes

Study countries

- Germany
- Netherlands
- Spain
- United Kingdom

Study description

What is the incidence of treatment-related intercurrent events common in clinical trials in patients with major depressive disorder?
Study objectives, to examine the proportion of patients with newly diagnosed major depressive disorder who start treatment with antidepressants, NSRIs, SSRIs, or other anti-depressants, as well as those who switch or discontinue treatment at specific intervals 4, 6, 8, 12, and 24 weeks after treatment initiation, stratified by age, sex, and country - database during the study period 2013 - 2022, to estimate the duration of antidepressant, use in patients with newly diagnosed major depressive disorder who initiate treatment with antidepressants, NSRIs, SSRIs, or other antidepressants, stratified by age, sex, and country - database during the study period 2013 - 2022, to assess the proportions of patients with newly diagnosed major depressive disorder who initiate, switch, or discontinue treatment with psycholeptics, antipsychotics, anxiolytics, hypnotics, and sedatives at specific intervals 4, 6, 8, 12, and 24 weeks after starting antidepressant therapy, stratified by age, sex, and country - database during the study period 2013 - 2022.

Study status

Finalised

Research institutions and networks

Institutions

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

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: 09/07/2026

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

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

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Primary lead investigator

Johnmary Arinze

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 27/07/2023

Actual: 27/07/2023

Study start date
Planned: 01/01/2013

Actual: 01/01/2013

Date of final study report
Planned: 30/12/2023

Actual: 03/06/2024

Sources of funding

- EMA

Study protocol

Study Protocol P2 C1-008 Version 3.1 final.pdf (693.82 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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

• Patient-level characterisation (Objective 1 and 3)

• Patient-level drug utilization (Objective 2)

Main study objective:

To examine the proportion of patients with newly diagnosed major depressive disorder who start treatment with antidepressants and psycholeptics and of those the proportion who switch or discontinue treatment by specific timepoints after treatment initiation, stratified by age group, sex, and country.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Major depression

Depression

Population studied

Short description of the study population

9.5.1 Patient-level characterization of MDD treatment

The study cohort comprised all patients, aged 12 years or older, with newly diagnosed MDD present in the respective databases during the study period (2013-2022) and with at least 365 days of data availability before this diagnosis.

9.5.2 Patient-level utilization of antidepressants

All individuals aged 12 and above who are new users of antidepressants with incident MDD diagnosis in the
period between 1st of January 2013 and 31st of December 2022 (or latest date available), with at least 1 year
of data visibility prior to the date of their first prescription of the antidepressant class of interest. Because in this selection of new users, the criterion of 365 days data available before the MDD diagnosis was not applied,
individuals can be included who were not included in the cohort of newly diagnosed MDD patients.

Age groups

- Adolescents (12 to < 18 years)
- 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

19.300.000

Study design details

Setting

This study was conducted using routinely collected data from 5 databases in 4 European countries (Germany, Spain, The Netherlands and the United Kingdom). All databases were previously mapped to the OMOP Common Data Model (CDM).

Outcomes

Treatment initiation, treatment discontinuation and treatment switch.

Data analysis plan

Percentage of patients initiating treatment with specific antidepressants or psycholeptics. Percentage of patients switching treatment to specific antidepressants or psycholeptics. Percentage of patients discontinuing treatment with specific antidepressants or psycholeptics. Estimation of the mean, median, 25th percentile, 75th percentile, minimum, and maximum durations of antidepressant use.

Documents

Study report

DARWIN_EU_D2.2.4_Report_P2-C1-008_MDD_V5.1.pdf (1.41 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)

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink (CPRD) GOLD

IQVIA Disease Analyzer Germany

Data sources (types)

Electronic healthcare records (EHR)

Other

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

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

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No