

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

First published: 03/10/2023

Last updated: 25/09/2024

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: 23/05/2025

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

Ilse Schuemie study@darwin-eu.org

Study contact

study@darwin-eu.org

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 type:

Non-interventional study

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

Population studied

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

19300000

Study design details

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