# Antidepressants withdrawal syndrome: a pharmacovigilance study in VigiBase®

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Study    Finalised

## Administrative details

**EU PAS number**

EUPAS41765

**Study ID**

41766

**DARWIN EU® study**

No

**Study countries**

☐ France

**Study status**

Finalised

## Research institutions and networks

# Institutions

## Toulouse University Hospital

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**Institution**

## CIC Inserm 1436

# Contact details

**Study institution contact**

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**Primary lead investigator**

Francois Montastruc

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Actual: 25/06/2021

**Study start date**

Actual: 25/06/2021

**Date of final study report**

Actual: 25/06/2021

# Sources of funding

- No external funding

# Study protocol

Study protocol_WD Sd Antidepressants.pdf (237.72 KB)

# Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

# Methodological aspects

# Study type

# Study type list

**Study topic:**

Human medicinal product

Disease /health condition

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Data collection methods:**

Secondary use of data

**Main study objective:**

Compare the risk of reporting withdrawal syndrome after discontinuation of short half-lives antidepressants and long half-lives antidepressants among Serotonin Reuptake Inhibitors (SRI), Serotonin and Norepinephrine Reuptake inhibitors (SNRI) and atypical antidepressants.

# Study Design

**Non-interventional study design**

Other

**Non-interventional study design, other**

Case/Non-case study

# Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

**Medical condition to be studied**

Antidepressant discontinuation syndrome

Drug withdrawal syndrome

Withdrawal syndrome

# Population studied

**Short description of the study population**

We will include all ICSRs registered between January 1, 1988, and December 31, 2020, with age and sex known. All patients aged 6 or older on the date of the reports and treated by an antidepressant among SRI, SNRI, tricyclic or atypical antidepressant (listed in Exposure definition) were included. Patients whose sex and age were unknown were excluded.

**Age groups**

- Children (2 to < 12 years)
- 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**

340000

# Study design details

**Outcomes**

Risk of reporting a withdrawal syndrome

**Data analysis plan**

Data will be extracted from VigiBase(R) Using a case/non-case design, we will perform a multivariate logistic regression to estimate reporting odds ratios (RORs) with their 95% confidence interval (CI). The reporting odds ratios (ROR) is the exposure odds among reported cases of withdrawal syndrome to the exposure odds among reported non-cases. Sensitivity analyses will be conducted (restricting analyses to physician reports only, to USA reports only, to the last 5 years only).

# 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.

**Conflicts of interest of investigators**

EUPAS41765-41762.pdf (165.01 KB)

**Composition of steering group and observers**

EUPAS41765_steering group.pdf (78.2 KB)

**Signed checklist for study protocols**

# Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Individual Case Safety Reports (ICSRs)

# Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No