Antidepressants withdrawal syndrome: a pharmacovigilance study in VigiBase®

First published: 25/06/2021

Last updated: 25/06/2021

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/41766

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

First published: 01/02/2024

Last updated: 01/02/2024

Institution

CIC Inserm 1436

Contact details

Study institution contact

Francois Montastruc

Study contact

francois.montastruc@univ-tlse3.fr

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

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

EUPAS41765-41764.pdf(446.49 KB)

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