Serotonin and norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors and other antidepressants and persistent sexual dysfunction - An EudraVigilance analysis

First published: 20/01/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39113

EU PAS number

EUPAS39112

Study ID

39113

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study was conducted to describe the case reports of persistent sexual dysfunctions to Serotonin and norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors and other antidepressants.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

Pinheiro Luis

Study contact

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Primary lead investigator

Pinheiro Luis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/12/2018

Actual: 07/12/2018

Study start date

Planned: 07/12/2018

Actual: 07/12/2018

Date of final study report

Planned: 13/02/2019

Actual: 26/02/2019

Sources of funding

- EMA

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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Case series review of Pharmacovigilance data

Data collection methods:

Secondary use of data

Main study objective:

Describe cases of Post-SSRI sexual dysfunction

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

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

CITALOPRAM

FLUOXETINE

FLUVOXAMINE

PAROXETINE

PAROXETINE ACETATE

SERTRALINE

DESVENLAFAXINE

FLUOXETINE HYDROCHLORIDE

PHENTERMINE HYDROCHLORIDE

OLANZAPINE

Medical condition to be studied

Loss of libido

Genital hypoaesthesia

Libido decreased

Female sexual arousal disorder

Anorgasmia

Female orgasmic disorder

Male orgasmic disorder

Additional medical condition(s)

Post-SSRI Sexual Dysfunctions

Population studied

Short description of the study population

Case reports of persistent sexual dysfunctions to Serotonin and norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors and other antidepressants.

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

3210

Study design details

Data analysis plan

Descriptive statistics were run on the totality of the cases with sexual dysfunctions, by reporter type, by substance, by class, by indication, by country, by age, gender and by previous medical history of sexual dysfunction. Results by reaction were stratified by core PSSD case definition (see 4.3.2.), extended terms definition, which are the remaining terms from the sexual

dysfunction case definition (see 4.3.1.) and secondary terms as per annex II.

Documents

Study results

Antidepressants and PSSD - EV analysis - report - 20190220.pdf(899.54 KB)

Data management

Data sources

Data source(s), other

EudraVigilance

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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