Deaths and life-threatening events associated with paliperidone palmitate in France

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37271

EU PAS number

EUPAS37270

Study ID

37271

DARWIN EU® study

No

Study countries

☐ France

Study description

Our aim was to describe paliperidone palmitate-related adverse drug reactions (ADRs) leading to death or life-threatening events, specifying their main clinical and pharmacological characteristics.This observational study was a retrospective review of French pharmacovigilance database cases in patients treated with PP between January 1, 2013, and December 31, 2019.

Study status

Finalised

Contact details

Study institution contact

DAVID BOELS

Study contact

david.boels@chu-nantes.fr

Primary lead investigator

DAVID BOELS

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/01/2020

Study start date

Actual: 15/01/2020

Data analysis start date
Actual: 20/01/2020

Date of final study report
Planned: 15/09/2020

Actual: 15/09/2020

Sources of funding

- Other

More details on funding

Nantes University hospital

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The main objective was to describe PP-related adverse drug reactions (ADRs) leading to death or life-threatening events, specifying their main clinical and pharmacological characteristics.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

Name of medicine

XEPLION

Population studied

Short description of the study population

Patients treated with paliperidone palmitate (PP) between January 1, 2013, and December 31, 2019.

Age groups

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

400

Study design details

Outcomes

Compare paliperidone palmitate mortality rate from the rates for oral risperidone and parenteral risperidone.

Data analysis plan

This observational study was a retrospective review of FPVD cases in patients treated with PP between January 1, 2013, and December 31, 2019. To approximate the number of patients exposed to PP or risperidone (oral and parenteral forms), we used data from the annual Medic’AM spreadsheet, which catalogs all drug reimbursements by the French health insurance system, and

the World Health Organization’s Defined Daily Doses (DDDs). The DDD is the average daily maintenance dose of a drug used for its main indication in adults. Mortality was calculated as the ratio of the number of deaths reported in the FPVD to the number of patients treated with PP or risperidone, over the study period.Continuous data was summarized with means and standard deviations, or medians. Categorical data was summarized with tallies and percentages, and they were compared using Fisher’s exact tests (two-sided, α =

Data management

Data sources

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