Pregabalin abuse in France : a national cohort study

First published: 15/07/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10298

Study ID

28047

DARWIN EU® study

No

Study countries

France

Study description

Pregabalin is a psychoactive drug indicated in neuropathic pain, generalized anxiety disorder and partial epilepsy. It modifies neuronal activity, binding α2δ1 presynaptic voltage-dependent calcic channel receptor, which is responsible for

its psychotropic action. Neuropsychiatric adverse drug reactions, such as euphoria, have been described. Pregabalin abuse has been suggested in a few toxicological studies, pharmacovigilance studies, and small surveys among opioid users or treated by opiate maintenance drugs. Despite signals of abuse in some European countries, no data suggest a potential for pregabalin abuse in France, and no study has ever compare pregabalin abuse to other drug used in the same indication. Searching a possible pregabalin abuse seems all the more relevant as its consumption increases in France and in Europe. This study aims to investigate pregabalin abuse and its frequency in the French general population, in comparison with other drugs used in similar indications and to determine the factors associated with pregabalin abuse.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse

France

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Institution **Educational Institution** **Hospital/Clinic/Other health care facility**

ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Maryse Lapeyre-Mestre

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/02/2015

Actual: 02/02/2015

Study start date

Planned: 06/04/2015

Actual: 01/06/2015

Data analysis start date

Planned: 04/05/2015

Actual: 15/06/2015

Date of final study report

Planned: 30/10/2015

Actual: 24/12/2015

Sources of funding

- Other

More details on funding

Toulouse University Hospital

Study protocol

Pregabalin study protocol 15_07.pdf (666.05 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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study will be to assess pregabalin abuse and its frequency in the French general population, in comparison to other drugs with similar indications (gabapentin and duloxetine), in a pharmacoepidemiological, observational, French national retrospective cohort study.The secondary objective is to determine the factors associated with abuse of each drug.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

PREGABALIN

GABAPENTIN

DULOXETINE

Population studied

Short description of the study population

French adult population of both gender, naive of any study medication or medication used in the same indication with abuse potential.
Patients must have the following criteria:
1. Aged 18 or more
2. New users of pregabalin, gabapentin of duloxetine between the first date of inclusion (15th of June 2006) and until 31th December 2012 (to grant a two-years minimum follow-up),
3. Subjects being reimbursed at least two delivery of medication group, at different dates (two delivery or more the same day, only once, will be considered as single time user)

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

15.000

Study design details

Outcomes

Occurrence of drug abuse along time will be the main outcome (abuse of pregabalin in pregabalin group, etc.). The abuse will be defined by the exceeding of maximum daily dose recommended. For every 3 drugs studies,

this maximum corresponds to 2 daily DDD

Data analysis plan

Outcome will be abuse of the cohort study drug, defined as a daily abuse above the maximum recommended dose. Abuse will be investigated through a Kaplan-Meier survival model. Factors associated with abuse will be investigated through a Cox proportional hazard regression model with time dependent covariates.

Documents

Study results

CR_CT022015033_pharmacodépendance_28_05_2015.pdf (468.24 KB)

Résumé pregabaline SFPT 2016.pdf (390.82 KB)

Study publications

Bossard JB, Ponté C, Dupouy J, Lapeyre-Mestre M, Jouanjus E. Disproportionality…

Driot D, Chicoulaa B, Jouanjus E, Dupouy J, Oustric S, Lapeyre-Mestre M.Pregaba…

Driot D, Jouanjus E, Oustric S, Dupouy J, Lapeyre-Mestre M. Patterns ofgabapent…

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

DOI Pregabalin.pdf (503.42 KB)

Composition of steering group and observers

Steering committe.pdf (90.97 KB)

Signed code of conduct

Compliance pregabalin.pdf (188.1 KB)

Signed code of conduct checklist

Annex2_Checklist Code of conduct pregabalin.pdf (1000.96 KB)

Signed checklist for study protocols

ENCePPChecklistforStudyProtocols pregabalin.pdf (1.18 MB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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

Unknown