An Evaluation of the Misuse and Abuse of Pregabalin using RADARS® System Programs in the United States and the European Union

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Study Finalised

Administrative details

EU PAS number

EUPAS24790

Study ID

29172

DARWIN EU® study

No

Study countries

France

Germany

Italy

United States

Study description

The primary objectives of this evaluation:1) Summarize misuse and abuse data for pregabalin and each comparator within each country for each data source2) Perform a statistical analysis of trends over time for pregabalin and each comparator to assess changes in misuse and abuse within each country and data source

Study status

Finalised

Research institutions and networks

Institutions

RADARS® System

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Institution

Cystic Fibrosis Trust

Contact details

Study institution contact

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Primary lead investigator

Kofi Asomaning

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/06/2018

Study start date

Planned: 15/06/2018

Actual: 15/06/2018

Data analysis start date

Planned: 30/06/2018

Actual: 30/06/2018

Date of final study report

Planned: 30/10/2018

Actual: 17/10/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

RADARS System Pregabalin Study Protocol 06June2018 FINAL.pdf (979.58 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

A0081363

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The primary objectives of this evaluation:1) Summarize misuse and abuse data for pregabalin and each comparator within each country for each data source2) Perform a statistical analysis of trends over time for pregabalin and each comparator to assess changes in misuse and abuse within each country and data source

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

Medical condition to be studied

Drug abuse

Population studied

Short description of the study population

Entire population enrolled by each data source

EUROPAD Program:

The surveillance population consists of individuals seeking treatment for substance use disorders (other than alcohol) at sites that offer treatment for opioid use disorders in France, Germany, and Italy.

Treatment Center Programs Combined:

The surveillance population consists of patients entering treatment for opioid dependence in the United States.

GTNet Program:

The surveillance population consists of exposure cases recorded by participating poison centres in France, Germany, and Italy.

National Poison Data System:

The surveillance population consists of exposure cases recorded by 55 regional poison control centers in all 50 states covering 100% of the total United States population.

Survey of Non-Medical Use of Prescription Drugs Program:

The surveillance population consists of the adult general population via an online survey panel company. The sample is stratified by United States Census region and gender, mirroring the distribution of the population in both percentage and gender representation (approximately 50% female, 50% male within each region). The samples from France, Germany and Italy are stratified

by gender and Nomenclature des unités territoriales statistiques (NUTS) 1 level regions.

Web Monitoring Program:

The Web Monitoring Program surveillance population consists of individuals within the United States who post statements related to misuse and abuse on public social media accounts, online blogs, web forums and other internet sites.

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

100

Study design details

Outcomes

Non medical useAbuse

Data analysis plan

The primary objective will be to estimate rates or prevalence estimates for each of the outcomes (non-medical use, misuse, abuse, intentional exposures) by program for pregabalin and comparators within each country using descriptive statistics.

Documents

Study results

RADARS summary.pdf (116.53 KB)

Data management

Data sources

Data sources (types)

Disease registry

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