Active Surveillance Program for Misuse, Abuse, Addiction, Overdose and Death Attributed to EMBEDA® and Other Oral Extended-Release Morphine

First published: 14/05/2016

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/36415

EU PAS number

EUPAS13456

Study ID

36415

DARWIN EU® study

No

Study countries

United States

Study description

To quantify the extent of misuse, abuse, addiction, overdose and death believed to be associated with each of two comparisons groups - Embeda and other oral ER morphine tablets and capsules - in the community over time
NOTE: THIS STUDY WAS TERMINATED PREMATURELY BECAUSE THE SPONSOR WITHDREW THE NDA FOR EMBEDA

Study status

Finalised

Research institutions and networks

Institutions

Rocky Mountain Poison & Drug Safety (RMPDS)

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Institution

Contact details

Study institution contact

Campbell Ulka

Study contact

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Primary lead investigator

Kenneth Petronis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/04/2015

Actual: 13/04/2015

Study start date

Planned: 30/09/2016

Actual: 30/09/2016

Date of final study report

Planned: 30/04/2020

Actual: 30/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

B4541022 Embeda PMR Protocol 14May2015 - GDMS.pdf(1.87 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

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

Data collection methods:

Primary data collection

Main study objective:

Estimate rates of misuse, abuse, addiction, overdose and death believed to be associated with EMBEDA and other oral extended release morphine tablets and capsules in the community over time

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Active surveillance

Study drug and medical condition

Name of medicine, other

Embeda

Medical condition to be studied

Pain

Population studied

Short description of the study population

The surveillance population will be specific to each RADARS System data source, as described below:

Treatment Center Program: The surveillance population consists of patients entering substance abuse treatment programs.

Poison Center Program: The surveillance population consists of exposure cases recorded by poison control centers in 46 states covering over 282 million people in urban, suburban, and rural regions (91.5% of total 2010 US population).

College Survey Program: The surveillance population consists of students attending a two- or four-year college, university or technical school at least part-time. Web Monitoring Program: The Web Monitoring Program surveillance population consists of individuals who post statements related to misuse, abuse, addiction, overdose and death on public social media accounts, online blogs, web forums and other internet sites.

Inclusion criteria

Treatment Center Program:

Subjects must meet all of the following inclusion criteria to be eligible for inclusion in the surveillance:

1. Completed the survey.
2. Age 18 years or older.
3. Provided a valid three digit zip code.
4. Reported past month use of any oral ER morphine tablet or capsule to get high.

Poison Center Program:

Cases must meet all of the following inclusion criteria to be eligible for inclusion in the surveillance:

1. Report of intentional human exposure to oral ER morphine tablets.

College Survey Program:

Subjects must meet all of the following inclusion criteria to be eligible for inclusion in the surveillance:

1. Indicates consent before providing any responses to the questionnaire.
2. Age 18 years or older.
3. Indicates is enrolled in a two- or four-year college, university or technical school at least part-time.
4. Reports non-medical use of any oral ER morphine tablet or capsule in the past 3 months.

Web Monitoring Program

1. Online posts originating in the United States which mention EMBEDA or other oral ER morphine tablets or capsules are eligible for inclusion in the surveillance.

Exclusion criteria

There are no exclusion criteria for subjects in the Treatment Center Program, the Poison Center Program or the Web Monitoring Program.

Respondents in the College Survey Program meeting any of the following criteria will not be included in the surveillance:

1. Answers affirmatively to any question about any use (past 3 months) of a non-existent drug.
2. Answers affirmatively to every question about frequency (more than 10 days per month) of illegal drug use.
3. Answers affirmatively to every question about any use (past 3 months) of prescription opioids and stimulants.
4. Three or more text field responses contain irregularities (eg, long strings of a single character, comment unrelated to the question)

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

0

Study design details

Outcomes

Misuse, Abuse, Addiction, Overdose, Death

Data analysis plan

The primary goal of the analyses will be to estimate rates of five safety-related endpoints (misuse, abuse, addiction, overdose, and death) associated with each of the two comparison groups. These rates will be estimated across time and by route of administration. A Poisson regression model with a drug group specific dispersion parameter will be utilized to estimate trends over time in rates for the two comparison groups. Evaluation of data from the Web Monitoring Program will be of a descriptive nature as it does not allow for the calculation of rates.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Surveillance of patients entering substance abuse treatment programs, Surveillance of calls to US poison centers, Repeated internet surveys of students attending a two- or four-year college, university or technical school at least part-time, Web monitoring of posts to public social media accounts, online blogs, web forums and other internet sites

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