A Post-Marketing Surveillance of the Abuse of Eluxadoline using Poison Centre Data in the United States and Canada

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37043

EU PAS number

EUPAS25247

Study ID

37043

DARWIN EU® study

No

Study countries

☐ Canada

United States

Study description

The primary objective is to quantify the rate of abuse and serious adverse events for eluxadoline during a 3-year post approval period

Study status

Finalised

Contact details

Study institution contact

Ahunna Ukah

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Ahunna Ukah

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/05/2018

Actual: 30/05/2018

Study start date

Planned: 01/01/2017

Actual: 01/01/2017

Data analysis start date
Planned: 01/11/2018

Date of interim report, if expected
Planned: 31/12/2018

Actual: 20/12/2018

Date of final study report
Planned: 31/07/2020

Actual: 24/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

Poison Center Eluxadoline Study Protocol 07AUG2018_Redacted.pdf(486.39 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

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

Observational surveillance

Data collection methods:

Secondary use of data

Main study objective:

To quantify the rate of abuse and serious adverse events for eluxadoline during a 3-year post approval period

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational surveillance

Study drug and medical condition

Name of medicine, other

Eluxadoline

Population studied

Short description of the study population

All cases of human exposure to eluxadoline recorded in the National Poison Data System from January 2017 to December 2019 and in the Canadian Poison Centre Network Program from January 2018 to December 2019 will be identified and included in the analyses.
Exposures confirmed to be non-exposures and non-human exposures will be excluded.

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

10000

Study design details

Outcomes

Rate of abuse and serious adverse events

Data analysis plan

• All cases of exposure to eluxadoline recorded in the National Poison Data System from January 2017 to December 2019 and in the Canadian Poison Centre Network Program from January 2018 to December 2019 will be identified and included in the analyses • Cases of eluxadoline exposure will be presented descriptively by patient demographics, reason and medical outcome, by quarter. Population-adjusted rates and 95% confidence intervals will be calculated using census data in order to adjust for exposure in the covered population quarterly and cumulatively

Documents

Study results

RADARS System Allergan EUPAS 25247 2019_Abstract.pdf(270.55 KB)

Study, other information

RADARS System Annual Study Report Allergan 2018_Abstract.pdf(29.44 KB)

Truberzi Canada_RADARS System (1st Interim Report Abstract).pdf(28.16 KB)

Data management

Data sources

Data source(s), other

American Association of Poison Control Centers, United States, Canadian Poison Centre Network Program, Canada

Data sources (types)

Other

Data sources (types), other

Observational surveillance

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