Loperamide and the risk of Brugada syndrome

First published: 28/10/2019

Last updated: 13/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/32005

EU PAS number

EUPAS32004

Study ID

32005

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Calculate incidence of Brugada syndrome in patients treated with loperamide products.

Study status

Finalised

Research institution and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Robert Flynn

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/01/2018

Actual: 15/01/2018

Study start date
Planned: 01/02/2018

Actual: 01/02/2018

Date of final study report
Planned: 05/03/2018

Actual: 05/03/2018

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

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:

Calculate the incidence of Brugada syndrome in patients treated with loperamide products.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

LOPERAMIDE

Medical condition to be studied

Brugada syndrome

Population studied

Short description of the study population

Patients with at least one loperamide prescription with one year minimum follow-up time in THIN since 2000 and with “acceptable” status (Patflag A or C). No restriction on age.

Age groups

Infants and toddlers (28 days – 23 months)

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

600000

Study design details

Outcomes

Brugada syndrome

Data analysis plan

Crude event rates (with 95% CI) were calculated as number of patients with events divided by the total number of patients exposed. The duration for time to event was calculated as the shortest time from exposure to event for each patient and then stratified into three categories (< 1 year, 1 to 5 years, > 5 years). For Brugada Syndrome this was summarised as median, minimum & maximum time in days.

Documents

Study results

Loperamide and Brugada syndrome results and short protocol.pdf(115.78 KB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

THIN

Data sources (types)

Electronic healthcare records (EHR)

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