

# Loperamide and the risk of Brugada syndrome

**First published:** 28/10/2019

**Last updated:** 13/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS32004

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### Study ID

32005

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

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

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### Study status

Finalised

# Research institutions 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

[robert.flynn@ema.europa.eu](mailto:robert.flynn@ema.europa.eu)

### Primary lead investigator

Robert Flynn

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/01/2018

Actual: 15/01/2018

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**Study start date**

Planned: 01/02/2018

Actual: 01/02/2018

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**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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**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

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**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.

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## **Age groups**

- Adolescents (12 to < 18 years)
  - Children (2 to < 12 years)
  - Infants and toddlers (28 days - 23 months)
  - 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)
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## **Estimated number of subjects**

600000

# Study design details

## **Outcomes**

Brugada syndrome

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## **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)

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## 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.

## Data sources

### Data source(s)

THIN® (The Health Improvement Network®)

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### Data source(s), other

THIN

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No