Misuse and Abuse of Loperamide in the United States

First published: 21/12/2016

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16778

Study ID

32664

DARWIN EU® study

No

Study countries

United States

Study description

This is a retrospective non-interventional study of secondary data sources to document the misuse and abuse of loperamide in the US. This study aims to characterize the abuse and misuse of loperamide in the US through the

evaluation of two independent surveillance data systems. The objectives of this study are: 1) to describe abuse and misuse of loperamide as reported to the National Poison Data System (NPDS) and 2) to describe non-medical use of loperamide as reported via an online survey of Non-Medical Use of Prescription Drugs (NMU-Rx) by a general adult population sample.

Study status

Finalised

Research institutions and networks

Institutions

Denver Health and Hospital Authority

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Richard Dart

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/10/2016

Actual: 20/10/2016

Study start date
Planned: 20/12/2016

Actual: 20/12/2016

Date of final study report
Planned: 27/09/2019

Actual: 30/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Johnson & Johnson Consumer Inc.

Study protocol

MA-161205104527-DHEP Protocol.pdf (265.78 KB)

LOP Study Protocol Amendment 1 approved 10Jul2019.pdf (212.55 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Other

Study topic, other:

Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Other

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

Epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The objectives of this study are: 1) to describe abuse and misuse of loperamide as reported to the National Poison Data System (NPDS)2) to describe non-medical use of loperamide as reported via an ongoing online survey of Non-Medical Use of Prescription Drugs (NMU-Rx) by a general adult population sample.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational database study

Population studied

Short description of the study population

NPDS data represent loperamide exposures reported to US poison centers from 2012 through 2015. These include patients of all ages and may be contacts made by the public or healthcare professionals.

NMU-Rx data represent information captured via an ongoing online survey of the general adult population who have registered to participate in online surveys in exchange for modest compensation. The NMU-Rx survey was conducted in July/August 2016.

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

40000

Study design details

Outcomes

NPDS data source• Population-based rate of loperamide abuse• Sales-based rate of loperamide abuse• Population-based rate of loperamide misuse• Sales-based rate of loperamide misuseNMU-Rx data source• Population-based rate of loperamide non-medical use• Sales-based rate of loperamide non-medical use, • Describe the populations at-risk for the misuse and abuse of loperamide and associated outcomes as reported to NPDS.• Describe the populations at-risk for non-medical use of loperamide and potential risk factors as reported to NMU-Rx.

Data analysis plan

Demographic characteristics for both NPDS and NMU-Rx will be summarized using descriptive analysis. Mean and standard deviation or median and interquartile range (IQR) will be calculated for continuous variables. Frequencies and proportions will be calculated for categorical variables.For NPDS, the main

summary measures will be patient demographics, exposure characteristics, level of healthcare facility, and medical outcome.For NMU-Rx, the main summary measures will be respondent demographics, respondent characteristics, lifetime use and non-medical use of loperamide, frequency of recent non-medical use of loperamide, as well as reason and route of non-medical use.

Documents

Study results

McNeil J&J Loperamide COMBINED v01_30Jun2017.pdf (1001.04 KB)

McNeil J&J Loperamide FINAL 13Nov2019.pdf (1.28 MB)

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 sources (types)

Other

Data sources (types), other

National Poison Data System administered by the American Association of Poison Control Center. Non-Medical Use of Prescription Drug Survey owned and operated by RADARS System.

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