Association between use of desloratadine and risk of seizures, supraventricular tachycardia, and atrial fibrillation or flutter: A Nordic register-based study

First published: 16/09/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15038

Study ID

30261

DARWIN EU® study

No

Study countries

Denmark

Finland

Norway

Sweden

Study description

This is an observational study to assess the potential risk of desloratadine exposure on seizures, supraventricular tachycardia, and atrial fibrillation or flutter. The study utilizes data from the Nordic national population registers that include all individuals who redeemed a prescription for desloratadine. The study will determine the incidence rate and examine the associations between desloratadine exposure and seizures, supraventricular tachycardia, and atrial fibrillation or flutter estimated from the registers and extrapolated to the general population.

Study status

Finalised

Research institutions and networks

Institutions

Department of Epidemiology, Institute of Applied Economics and Health Research (ApHER)

Denmark

First published: 22/02/2013

Last updated: 01/07/2019

Institution | Outdated | EU Institution/Body/Agency | ENCePP partner

National Institute of Public Health, University of Southern Denmark Denmark, University of Tampere Finland, Lund University Sweden, Norway-being coordinated by Lund University Sweden

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anders Green

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/04/2013

Study start date

Planned: 09/11/2016

Actual: 09/11/2016

Data analysis start date
Planned: 28/02/2019

Actual: 15/02/2019

Date of final study report
Planned: 30/06/2019

Actual: 10/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Study protocol

MK-4117-203-01 Protocol Summary.pdf (657.33 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

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:

Data from the Nordic national population registers will be used in this prospective observational cohort study of individuals who redeemed a prescription for desloratadine to determine the incidence rate and examine the associations between desloratadine exposure and seizures, supraventricular tachycardia, and atrial fibrillation or flutter.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational cohort

Study drug and medical condition

Medical condition to be studied

Rhinitis allergic

Urticaria chronic

Population studied

Short description of the study population

All individuals in three Nordic countries (Denmark, Finland and Sweden) who redeemed at least one prescription for DL or who received a diagnosis of seizure, SVT, or A-fib/flu.

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

365500

Study design details

Outcomes

The primary outcomes are to describe the use of desloratadine in the general population, describe the incidence rate of seizure, supraventricular tachycardia, and atrial fibrillation or flutter, and compare the risk of incident seizure, supraventricular tachycardia, and atrial fibrillation or flutter in individuals exposed to desloratadine to the risk among the same individuals while not exposed. The secondary outcomes are to describe the incidence rate of first recurrent seizure and to compare the risk of first recurrent seizure in individuals exposed to desloratadine to the risk among the same individuals while not exposed after adjusting for relevant confounding factors.

Data analysis plan

Descriptive analysis will be performed for the distribution of prevalent and incident use of desloratadine and for the number of redeemed prescriptions. Incidence rates (IR) of the events of seizures, supraventricular tachycardia, and atrial fibrillation or flutter with 95% confidence intervals will be determined. The association between exposure to desloratadine and these events will be evaluated using Poisson regression and the measure of effect will be incidence rate ratios (IRR).

Documents

Study results

MK-4117-203-final report_Final Redaction.pdf (9.18 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)

Administrative healthcare records (e.g., claims)

Drug registry

Other

Data sources (types), other

The data sources for this study include prescription registers, national patient registers, and civil registers from Denmark, Finland, Norway and Sweden.

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

Unknown