Association between use of desloratadine and risk of seizures, supraventricular tachycardia, and atrial fibrillation or flutter: A Nordic register-based study (MK-4117-205)

First published: 06/07/2020

Last updated: 24/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS35911

Study ID

38013

DARWIN EU® study

No

Study countries

Denmark

Finland

Norway

Sweden

Study description

This is an observational, nationwide, register-based study using person-specific linkage of data from the national population registers from Denmark, Finland, Norway, and Sweden (" Nordic countries") including all individuals who redeemed a prescription of desloratadine and all individuals with a registered diagnosis of seizure, supraventricular tachycardia, or atrial fibrillation or flutter. The objective is to explore the use of desloratadine (DL) in the general population (Substudy 1), to describe the incidence rate (IR) of first seizure (Substudy 2A), to examine the associations between DL exposure and risk of first seizure (Substudy 2B), to describe the IR of supraventricular tachycardia (SVT) (Substudy 3A), to examine the association between DL exposure and SVT (Substudy 3B), to describe the IR of atrial fibrillation or flutter (A-Fib/A-Flu) (Substudy 4A), and to examine the associations between DL exposure and A-Fib/A-Flu (Substudy 4B).

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

First published: 01/02/2024

Last updated: 08/07/2025

Institution | Pharmaceutical company

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

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

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Primary lead investigator

Annette Ersboll

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/01/2020

Actual: 16/01/2020

Study start date
Planned: 30/07/2020

Actual: 30/07/2020

Data analysis start date
Planned: 30/09/2020

Actual: 30/09/2020

Date of final study report
Planned: 31/12/2020

Actual: 05/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Study protocol

MK-4117-205-00-v1-Prot_L1-final-redaction.pdf (6.71 MB)

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:

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:

The objective is to explore the use of desloratadine (DL) in the general population, to describe the incidence rate (IR) and examination of association between DL exposure and first seizure, first SVT, first A-Fib/A-Flu.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational case-study design with use of register-based data

Study drug and medical condition

Medical condition to be studied

Seizure

Supraventricular tachycardia

Atrial fibrillation

Atrial flutter

Population studied

Short description of the study population

The cohort of individuals with redeemed DL prescriptions will be identified from the four Nordic national prescription registers. Similarly, the cohort of all individuals with seizures (first seizure), the cohort of individuals with SVT, and the cohort of individuals with A-fib/flu will be identified from the four Nordic national patient registers. The population is comprised of all individuals with DL prescriptions and of all individuals with seizures, SVT, or A-fib/flu in the four Nordic countries in the period 2001–2015 in Denmark and Finland, 2008–2015 in Norway, and July 2005–2015 in Sweden.

Inclusion criteria

Substudy 1

- Individuals who have redeemed at least one prescription of DL during the

study period (DL cohort) and have residential location in Denmark, Finland, Norway, or Sweden.
- General population living in Denmark, Finland, Norway, and Sweden on 01 January of each year.

Substudy 2A
- Individuals who have experienced a seizure during the study period (seizure cohort) and have residential location in Denmark, Finland, Norway, or Sweden.
- General population living in Denmark, Finland, Norway, and Sweden on 01 January of each year.

Substudy 2B
- Individuals who have redeemed at least one prescription of DL during the study period (DL cohort) and have residential location in Denmark, Finland, Norway, or Sweden.

Substudy 3A
- Individuals who have experienced a SVT during the study period (SVT cohort) and have residential location in Denmark, Finland, Norway, or Sweden.
- General population living in Denmark, Finland, Norway, and Sweden on 01 January of each year.

Substudy 3B
- Individuals who have redeemed at least one prescription of DL during the study period (DL cohort) and have residential location in Denmark, Finland, Norway, or Sweden.

Substudy 4A
- Individuals who have had an A-fib/flu diagnosis during the study period (A-fib/flu cohort) and have residential location in Denmark, Finland, Norway, or Sweden.
- General population living in Denmark, Finland, Norway, and Sweden on 01 January of each year.

Substudy 4B

- Individuals who have redeemed at least one prescription of DL during the study period (DL cohort) and have residential location in Denmark, Finland, Norway, or Sweden.

Exclusion criteria

Substudy 2A

- Individuals with a diagnosis of seizure, epilepsy, or prescriptions of antiepileptic medicine before entering the study period, as they have prevalent disease.
- Individuals with a diagnosis of malignant brain tumor or head trauma before the first seizure, as they are at high risk of seizures due to causes other than DL use.

Substudy 2B

- Individuals with a diagnosis of seizures, epilepsy, prescriptions of antiepileptic medicine, malignant brain tumor, or head trauma before redemption of first DL prescription, as they have prevalent disease or are at high risk of seizures due to causes other than DL use.
- Individuals with a brain tumor (benign and malignant), initiation of treatment with antiepileptic medicine, or head trauma occurring after beginning of DL use will be censored at date of first occurrence, as they are at high risk of seizures due to causes other than DL use.

Substudies 3A and 4A

- Individuals with a diagnosis of SVT or A-fib/flu before entering the study period, as they have prevalent disease.
- Individuals with a diagnosis of congenital pre-excitation syndrome (e.g., Wolff Parkinson White) before entering the study period, as they are at high risk of cardiac SVT or A-fib/flu due to causes other than DL use.

Substudies 3B and 4B

- Individuals with a diagnosis of SVT or A-fib/flu before use of DL, as they have prevalent disease.

- Individuals with a diagnosis of congenital pre-excitation syndrome (e.g., Wolff Parkinson White) before use of DL, as they are at high risk of SVT or A-fib/flu due to causes other than DL.

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Seizure, supraventricular tachycardia, or atrial fibrillation or flutter patients

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Estimated number of subjects

365.500

Study design details

Outcomes

IR of first seizure diagnosis, first SVT diagnosis, and first A-Fib/A-Flu diagnosis in patients administered DL

Data analysis plan

A descriptive analysis of DL use in the general population will be performed. Furthermore, the incidence rates of seizure, SVT, A-Fib/A-Flu, and first recurrent seizure will be calculated. Among persons ever dispensed DL, the associations between DL exposure and first seizure, SVT, A-Fib/A-Flu, and first recurrent seizure will be evaluated using Poisson regression of incidence rates accounting for confounding factors. Additional supplementary analyses will be performed.

Documents

Study results

MK-4117-205-final-report-nov-2020_Final Redaction.pdf (6.63 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

No