

Prevalence of narcolepsy in two European countries - France and Germany

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Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/48037>

EU PAS number

EUPAS48036

Study ID

48037

DARWIN EU® study

No

Study countries

France

Germany

Study description

The prevalence of narcolepsy in Europe is unclear at the moment due to contradictory studies and to the impact of the H1N1 vaccination on the overall prevalence. An updated prevalence for this condition is required for regulatory purposes. The main objective of this study was to provide the yearly prevalence of narcolepsy in France and Germany primary care settings, between 2011 and 2019. The yearly prevalence was stratified by sex and age group.

Study status

Finalised

Research institution and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Primary lead investigator

Hedenmalm Karin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned:

15/10/2021

Actual:

15/10/2021

Study start date

Planned:

15/10/2021

Actual:

15/10/2021

Date of final study report

Planned:

25/10/2021

Actual:

25/10/2021

Sources of funding

- EMA

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

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary data collection

Main study objective:

The main objective of this study was to provide the yearly prevalence of narcolepsy in France and Germany primary care settings, between 2011 and 2019. The yearly prevalence was stratified by sex and age group.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

Medical condition to be studied

Narcolepsy

Population studied

Short description of the study population

The study population included patients with narcolepsy registered in the general practices and paediatric practices in Germany and France between 2011 and 2019.

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)

Special population of interest

Other

Special population of interest, other

Patients with narcolepsy

Estimated number of subjects

5299939

Study design details

Outcomes

Narcolepsy

Data analysis plan

The numerator for the yearly prevalence consisted of patients that were diagnosed with narcolepsy during the year or that already had a history of narcolepsy at the start of the year. The denominator consisted of patients that were observable for at least one day during the respective year. The observability for a patient started on the date of the first visit to the practice and ended on the date of the last visit to the practice. The prevalence was expressed as number of narcolepsy cases per 10,000 persons. Yearly prevalence was stratified by sex and age group.

Documents

Study results

[Final study report Prevalence of Narcolepsy in Europe_SK_KH.pdf](#)(569.62 KB)

Data management

Data sources

Data source(s)

Disease Analyzer - OMOP
Disease Analyzer Germany

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