Tramadol prescribing: a drug utilisation study using electronic data from France, Germany and the UK

First published: 11/05/2017

Last updated: 30/01/2025

Study Finalised

Administrative details

EU PAS number

EUPAS19066

Study ID

29261

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

Study description

These studies will examine patterns of tramadol prescribing using data from France, Germany and the UK between 2006 and 2016.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

European Medicines Agency

Contact details

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Study contact

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Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/10/2016

Actual: 10/10/2016

Study start date
Planned: 03/10/2016

Actual: 10/10/2016

Date of final study report
Planned: 31/07/2017

Actual: 18/12/2017

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The objectives of the study are to examine patterns of tramadol prescribing between 2006 and 2016 using data from France, Germany and the UK, with a focus on incident and prevalent tramadol prescribing, dose and duration of tramadol prescribing, clinical indications for tramadol prescribing.

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

TRAMADOL

Population studied

Short description of the study population

Adult patients who were prescribed with tramadol in general practice and continuously provided data over a 10-year period from 1 January 2006 to 30

June 2016 from French and German primary care electronic health record data from IMS® Disease Analyzer (October 2016 release).

Age groups

- 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

100.000

Study design details

Outcomes

Trends in incident and prevalent tramadol prescribing overall and by age and gender. Clinical conditions recorded for people prescribed tramadol.

Data analysis plan

A descriptive analysis and yearly trends of tramadol prescribing will be measured in each database. The numerator will consist of a) patients prescribed tramadol and b) number of tramadol prescriptions. The denominator will consist of all other patients present in the database during the same year. Dose and duration of tramadol will be calculated using prescription information, with complete case analysis and imputation for missing prescription data applied.

Documents

Study results

Prescribing patterns of tramadol in adults in IMS.pdf (165.49 KB)

Study publications

Hedenmalm, K., Slattery, J., Skibicka-Stepien, I. et al. Prescribing patterns o...

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®)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

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