DARWIN EU® - Prescription trends of ketamine and esketamine

First published: 13/01/2025

Last updated: 06/05/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000436

Study ID

1000000436

DARWIN EU® study

Yes

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

Ketamine and esketamine are authorised for use in anaesthesia and for sedation in medical procedures, as well as for managing treatment-resistant depression.

The non-medical use of ketamine has become a growing concern within the European Union (EU), prompting law enforcement actions to monitor its illicit trafficking and misuse.

To better understand the scope of this issue, we initiated a study to examine legitimate prescription trends for ketamine and esketamine separately.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution **Educational Institution** **ENCePP partner**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dina Vojinovic

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/10/2024

Actual: 07/10/2024

Study start date

Planned: 13/12/2024

Actual: 13/12/2024

Date of final study report

Planned: 14/03/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C1-017_Ketamine_esketamine_V3.pdf(822.44 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

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

prescription trends of ketamine and esketamine over the last 10 years in Europe

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely collected health data from 6 data sources.

Main study objective:

1. To estimate the monthly and annual incidence rate for ketamine and for esketamine prescriptions, overall and stratified by age, sex, route of administration and country/database.
2. To estimate the monthly and annual prevalence for ketamine or esketamine prescriptions, overall and stratified by age, sex, route of administration and country/database.
3. To characterise individuals initiating treatment with ketamine or esketamine in terms of demographics, indication for prescribing, comorbidities and concomitant medication at the treatment initiation. Results will be stratified by country/database.
4. To estimate the initial dose at treatment initiation, treatment duration of the first drug era and cumulative duration of use for ketamine and for esketamine, where available. Results will be stratified by database.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N01AX03) ketamine

ketamine

(N01AX14) esketamine

esketamine

(N06AX27) esketamine

esketamine

Population studied

Short description of the study population

The study population will include all individuals registered in the data source between 1st of January 2014 and 31st of December 2023, with at least 1 year of data visibility prior to becoming eligible for study inclusion. Additional eligibility criteria will be applied for:

• Incidence rates calculation: the observation time of participants prescribed ketamine or esketamine is excluded during use and 1 year afterwards.

• Incidence rates and prevalence calculation stratified by age, sex and route of administration: age specific cohorts will have age-boundary eligibility criteria, sex specific cohorts will have sex eligibility criteria and cohort defined based on the route of administration will have route of administration eligibility criteria.

Patient-level utilisation of ketamine and esketamine

All new users of ketamine and esketamine in the period between 1st of January 2014 and 31st of December 2023 (or latest date available). Notably, all individuals need to have at least 1 year of data visibility prior to the date of their new prescription. “New use” refers to a prescription/dispensation of ketamine or esketamine in the study period and without any use of respective medicine in the previous 1 year.

Data management

Data sources

Data source(s)

Clinical Data Warehouse of the Bordeaux University Hospital

Clinical Practice Research Datalink (CPRD) GOLD

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

Institut Municipal d'Assistència Sanitària Information System

Disease Analyzer - OMOP

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown