Drug utilization study of dexamfetamine in European countries (DUS of dexamfetamine)

First published: 27/10/2014

Last updated: 04/10/2021

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43102

EU PAS number

EUPAS7778

Study ID

43102

DARWIN EU® study

No

Study countries

☐ Denmark

- [ ] Finland
- [ ] Germany
- [ ] Ireland
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

This is a retrospective database analysis to provide data on drug utilization on an annual basis for up to 5 years. Objectives are • to describe how dexamfetamine is prescribed in Europe • to evaluate off-label use in Europe • to collect data on abuse, misuse, overdose, diversion and dependence related to dexamfetamine

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

- [ ] United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dieter Fritsch

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/10/2014

Actual: 27/04/2016

Study start date

Planned: 30/09/2015

Actual: 01/05/2016

Data analysis start date

Planned: 01/06/2016

Actual: 01/06/2016

Date of interim report, if expected

Planned: 13/11/2018

Actual: 13/11/2018

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

Actual: 14/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Medice

Study protocol

Dexamfetamine DUS Protocol V2-1 08-09-2015 privacy.pdf(500.86 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

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:

• to describe how dexamfetamine is prescribed in Europe • to evaluate off-label use in Europe • to collect data on abuse, misuse, overdose, diversion and dependence related to dexamfetamine

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06BA02) dexamfetamine

dexamfetamine

Population studied

Short description of the study population

For the DUS patients who have been prescribed dexamfetamine at least once during the study period.

A: Identification of reporting sources

Inclusion criteria

•European countries, Denmark, Germany, Netherlands, Norway, UK

•Review, surveys, chart review, medical records, monitoring,

•Monitoring centers, databases, poison control centers

•Stimulants

•Abuse, misuse, overdose, diversion and dependence, problem drug use, non-medical drug use, addiction

Exclusion criteria

•Centers and databases from outside of EU

•Testing methods

B: Identification of information on abuse, misuse, overdose, diversion and dependence associated with dexamfetamine/lisdexamfetamine

Inclusion criteria

•European countries, Denmark, Germany, Netherlands, Norway, UK

•Literature review, surveys, interviews, chart review, medical records, monitoring

•Dexamphetamine, dextroamphetamine, Dexamfetamine, dextroamfetamine, lisdexamfetamine, lisdexamphetamine, Attentin, Dexamed, Dexedrine, other trade names for dexamfetamine, Elvanse, Vyvanse

•Abuse, misuse, overdose, diversion and dependence, problem drug use, non-medical use, addiction

Exclusion criteria

•Reports from outside the EU

•Only information on methylphenidate, only information on stimulants and amphetamine in general

•Reports which only describe use of substances where the use of an authorised medicinal product can be excluded (e.g. different galenic formulations)

•Substance use disorder

•Testing methods

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 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

500

Study design details

Data analysis plan

For the DUS, the analysis of databases will be done descriptively. A detailed statistical analysis plan (SAP) will be agreed on prior to the start of the analysis. Information from drug monitoring centers and poison control centers, other databases, literature and internet searches will be summarized per reporting period and compared with the findings from previous reports.

Documents

Study results

Dexamfetamine DUS Executive Summary on Final Report V1 02-11-2020.pdf (118.77 KB)

Study, other information

Dexamfetamine DUS Abstract of Final Report DAT V2 25-05-2021 privacy.pdf (110.87 KB)

Dexamfetamine DUS Abstract of Final Report LIT V2 28-05-2021 privacy.pdf (74.37 KB)

Data management

Data sources

Data source(s)

Danish registries (access/analysis)

Data source(s), other

Deutsche Beobachtungsstelle für Drogen und Drogensucht (DBDD) Germany, TRIMBOS Netherlands, SIRIUS Norway, Department of Health United Kingdom

Data sources (types)

Drug registry

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