Drug utilization study with VYVANSE® (lisdexamfetamine dimesilate) in Australia for Binge Eating Disorder

First published: 28/04/2021

Last updated: 14/03/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS40690

Study ID

47852

DARWIN EU® study

No

Study countries

Australia

Study description

This study will check how and to whom Vyvanse is prescribed in Australia by retrospectively analyzing a prescription database with additional information provided by a physician survey.

Study status

Finalised

Research institutions and networks

Institutions

Shire

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Study Contact Shire ClinicalTransparency@shire.com

Study contact

ClinicalTransparency@shire.com

Primary lead investigator

Study Contact Shire

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 09/05/2017

Study start date
Actual: 01/06/2019

Data analysis start date
Actual: 01/08/2019

Date of interim report, if expected
Actual: 30/10/2020

Date of final study report
Actual: 15/10/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Shire

Study protocol

SHP489-827-protocol-original-redact.pdf (4.24 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

CT.gov: NCT04866043,To obtain more information on the study, click here/on this link: https://clinicaltrials.takeda.com/study-detail/60901ad9f89629001e47b504

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The overall objective is to provide data on an annual basis for 3 years in Australia to evaluate drug utilization of VYVANSE® with a special interest in BED and to monitor off-label use

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06BA12) lisdexamfetamine

lisdexamfetamine

Medical condition to be studied

Binge eating

Population studied

Short description of the study population

Patients who are prescribed VYVANSE® and describe prescribing patterns of VYVANSE® among physicians in Australia.

Patients must meet the following inclusion criterion and not meet the follow exclusion criterion to be eligible for the analysis:

Inclusion criterion:

o Physician entered data for the patient until at least question 3 (Q03; main indication).

Exclusion criterion:

o Physician entered ADHD as main indication for prescription of VYVANSE® (Q03) for the patient.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

150

Study design details

Outcomes

1.Number of Participants Based on Indication of Use of Lisdexamfetamine Dimesylate, 1.Number of Participants Based on Patterns of Drug Use 2.Number of Participants Based on Average Daily Dose 3.Number of Participants Based on Maximum Daily Dose 4.Number of Participants Based on Co-prescription 5.Number of Participants Based on Co-diagnosis 6.Number of Prescriptions of Lisdexamfetamine Dimesylate 7.Treatment Duration

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Data analysis plan

Over the assessment period of three years, prescriptions recorded in the NostraData database from each 12-month reporting period as well as from the complete period at that time will be analysed using descriptive statistics.

Documents

Study results

SHP489-827-clinical-study-report-redact.pdf (161.67 KB)

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)

Other

Data sources (types), other

Prescription event monitoring, Retrospective database analysis, Physician survey

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