Drug utilization study for Elvanse® / Tyvense® / Elvanse® Adult in Europe

First published: 26/09/2016

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15507

Study ID

44400

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] Germany
- [ ] Ireland
- [ ] Norway
- [ ] Spain

- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

This is a multi-country drug utilization study using retrospective database analysis. A single database for all target countries is not available. Therefore, a study approach was chosen which includes multiple data sources to gather drug utilization data for Elvanse®/Tyvense® in European target countries. The study’s objective is to provide data on an annual basis for up to 5 years.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

- [ ] France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dorothea von Bredow

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/07/2013

Study start date

Actual: 21/02/2014

Data analysis start date

Actual: 24/02/2014

Date of interim report, if expected

Actual: 09/04/2014

Date of final study report

Planned: 31/03/2018

Actual: 12/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Shire Pharmaceuticals

Study protocol

SHP489-813 Elvanse DUS Protocol Version 3.0_26Feb2018 _clean_Redacted.pdf
(3.87 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Overall objective: The study’s objective is to provide data on an annual basis for the next 5 years in European countries to evaluate drug utilization. Study objectives:1. To characterize patients who are prescribed Elvanse®/Tyvense®2. To describe prescribing patterns of Elvanse®/Tyvense® among physicians3. To describe usage patterns of Elvanse®/Tyvense® among patients

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06BA12) lisdexamfetamine

lisdexamfetamine

Medical condition to be studied

Attention deficit hyperactivity disorder

Population studied

Short description of the study population

Patients who have been prescribed Elvanse® / Tyvense ® at least once during the study period.

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 attention deficit hyperactivity disorder

Estimated number of subjects

50000

Study design details

Data analysis plan

The analysis will be done descriptively as specified in the statistical analysis plan.

Documents

Study results

SHP489-813 Elvanse DUS Fifth R_FINAL_Watermarked.pdf (1.27 MB)

Study publications

Siffel C, Page M, Maxwell T, Thun B, Kolb N, Rosenlund M, von Bredow D, Keja J...

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)

Clinical Practice Research Datalink

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data sources (types)

Drug dispensing/prescription data

Drug registry

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