Strattera patient exposures and adherence in the United Kingdom, Germany, the Netherlands, and Sweden: 2018 Bi-annual assessment report (B4Z-MC-B026)

First published: 06/02/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17371

Study ID

28855

DARWIN EU® study

No

Study countries

Germany

Netherlands

Sweden

United Kingdom

Study description

The objective of this study is to describe atomoxetine (Strattera) utilization patterns for patients treated in the United Kingdom (UK), Germany, the Netherlands, and Sweden from the time period of 2012 through 2016.

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

Kristin Meyers meyers_kristin_joy@lilly.com

Study contact

meyers_kristin_joy@lilly.com

Primary lead investigator

Kristin Meyers

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/08/2013

Actual: 26/08/2013

Study start date

Planned: 01/04/2017

Actual: 01/04/2017

Date of final study report

Planned: 30/03/2018

Actual: 12/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B026 PASS.pdf (369.82 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective is to describe atomoxetine (Strattera) utilization patterns for patients treated in Germany, United Kingdom, Sweden, and the Netherlands.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06BA09) atomoxetine

atomoxetine

Population studied

Short description of the study population

Patients treated with Strattera in the United Kingdom (UK), Germany, the Netherlands, and Sweden from the time period of 2012 through 2016.

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)
- 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)

Estimated number of subjects

37314

Study design details

Outcomes

Patient exposures, patient discontinuation and adherence, and descriptive statistics.

Data analysis plan

For each country, patient counts will be provided for the most recent 5 calendar years. Counts and proportions will be tabulated by country, year, age group, gender, and formulation (capsule/oral solution). Patient exposures, including treatment duration, daily average dose, and frequent comorbid diagnoses will be presented (where available). Measures of utilization will be described for new users within the most recent 24 month follow-up for capsule users and 18 month follow-up for oral solution users. This includes: 1) percentage of patient discontinuation, reinitiation, and adherence, 2) mean and median length of therapy, as well as daily dose, and 3) distribution of the percentage of patients having undergone one or more recent treatment episodes over the follow-up period. Descriptive statistics will include patient count/frequencies by age, gender and formulation. Common comorbidities and concomitant medications will be summarized.

Documents

Study results

B026 PASS_Redacted (1).pdf (1008.63 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 source(s)

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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Data source(s), other

Longitudinal Prescription Data - Netherlands

Data sources (types)

Administrative healthcare records (e.g., claims)

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

Unknown