Strattera patient exposures and adherence in the United Kingdom, Germany, the Netherlands, and Sweden: 2016 Bi-annual assessment report. (B4Z-MC-B025)

First published: 29/09/2015

Last updated: 23/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS10786

Study ID

14862

DARWIN EU® study

No

Study countries

Germany

Netherlands

Sweden

United Kingdom

Study description

The objective of this study is to describe atomoxetine utilisation patterns for patients treated in the United Kingdom, Germany, the Netherlands, and Sweden from the time period of 2008 through 2014. This will be done by:-Estimating number of patients exposed, stratified by age-Estimating duration of exposure, medication possession ratio, and dose over the most recent 24 months-Estimating number of patients restarting, gap between, and duration of additional exposures over most recent 24 months, for those who stopped taking Strattera-Describing common comorbidity and concomitant medications

Study status

Finalised

Research institutions and networks

Institutions

IMS Health

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Meyers Kristin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/08/2013

Actual: 26/08/2013

Study start date

Planned: 01/10/2015

Actual: 01/10/2015

Data analysis start date

Planned: 01/02/2016

Date of final study report

Planned: 31/03/2016

Actual: 21/03/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B025 PASS.pdf (326 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 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 in the United Kingdom, Germany, the Netherlands, and Sweden from the time period of 2008 through 2014.

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

38.152

Study design details

Outcomes

Patient exposures, patient discontinuation and adherence, and descriptive statistics

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Data analysis plan

For each country, patient counts will be provided for the most recent 7 full calendar years. Counts and proportions will be tabulated by country, year, age group, and gender.Patient exposures, including treatment duration, duration of

exposure, daily average dose, and frequent comorbid diagnoses will be presented (where available).Measures of drug utilisation will be described for new users within the most recent 24 month follow-up period. This includes: 1) percentage of patient discontinuation, reinitiation, and adherence, 2) mean and median length of therapy, as well as daily dose, and 3) the distribution of the percentage of patients having undergone one or more treatment episodes over the 24 month observation period.Descriptive statistics including frequencies and proportions of patient count and demographics such as age and gender will be provided, as well as for population characteristics such as common comorbidities and concomitant medications.

Documents

Study results

B025 PASS_Final study report_Abstract.pdf (99.7 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.

Conflicts of interest of investigators

B025 PASS_Final study report.pdf (602.53 KB)

Data sources

Data source(s)

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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Data source(s), other

Disease Analyzer United Kingdom, Longitudinal Prescription Data (IMS) Germany

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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

No