Strattera patient exposures and adherence in the United Kingdom, Germany, the Netherlands, and Sweden: 2014 Bi-annual assessment report

First published: 03/04/2014

Last updated: 30/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20485

EU PAS number

EUPAS6305

Study ID

20485

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 Germany, United Kingdom (UK), Sweden, and the Netherlands

Study status

Finalised

Research institution 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

Kellier Nicole

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/08/2013

Actual: 16/08/2013

Study start date

Planned: 01/01/2014

Actual: 01/01/2014

Data analysis start date

Planned: 01/01/2014

Actual: 01/01/2014

Date of final study report

Planned: 28/03/2014

Actual: 09/04/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

EU DUS PASS.pdf(316.93 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 of this study is to describe atomoxetine (Strattera) utilization patterns for patients treated in Germany, United Kingdom (UK), 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

All patients with filled prescriptions of Strattera for the longest available duration in each selected database. In order to be eligible for inclusion patients will need at least two consecutive filled prescriptions.

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

0

Study design details

Outcomes

Patient exposuresPatient discontinuation and adherenceDescriptive statistics

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Data analysis plan

For each country, patient counts will be provided for the most recent 5 full calendar years, and the moving annual total (MAT) will be provided for midyear of the most recent year of available data, when appropriate. Patient exposures including treatment duration, duration of exposure, daily average dose, and frequent comorbid diagnoses will be presented (where available). Patient discontinuation and adherence will be described, including the percentage of

patients reinitiating therapy and the percentage of patients remaining on therapy at monthly time intervals. This will include data on mean and median length of therapy as well as mean daily dose.Descriptive statistics including frequencies and proportions of patient count and demographics such as age and gender will be provided as well as frequencies and proportions for population characteristics such as common comorbidities and concomitant medication.

Documents

Study results

StratteraB022 EUPASS_2014DUS_upload.pdf(805.17 KB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

Longitudinal prescription data Germany, Disease analyzer United Kingdom

Data sources (types)

Administrative data (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