Physician Survey to Assess Effectiveness of Strattera Risk Minimisation Activities in Prescribers Treating Adult Patients with ADHD

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20488

EU PAS number

EUPAS6486

Study ID

20488

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Netherlands
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

This is a cross-sectional survey to be administered in Denmark, Sweden, the Netherlands, Spain, and the UK among psychiatrists who prescribe Strattera and/or monitor adult patients treated with Strattera.

Study status

Finalised

Research institutions and networks

Institutions

GfK Health

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicole Kellier

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/02/2014

Actual: 03/02/2014

Study start date

Planned: 27/06/2014

Actual: 27/06/2014

Date of final study report

Planned: 30/01/2015

Actual: 20/11/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B028 RMiP PASS Protocol_1.pdf(85.09 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:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The main objective of this a survey is to assess the knowledge and awareness of Strattera risk minimisation measures among psychiatrists who prescribe Strattera or monitor adult patients treated with Strattera. The secondary objective includes an assessment of awareness of the available risk minimisation tools.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06BA09) atomoxetine

atomoxetine

Population studied

Short description of the study population

Psychiatrists who prescribe Strattera and/or monitor adult patients treated with Strattera in Denmark, Sweden, the Netherlands, Spain, and the UK.

Age groups

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

250

Study design details

Outcomes

Awareness, knowledge and adherence will be evaluated and expressed as proportions

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Data analysis plan

Data analyses will be descriptive and will entail tabular displays of mean values and the frequency distribution of item responses. Results will be expressed as proportions and means. Summary tables will include descriptive statistics for continuous variables (means) and categorical variables (frequencies, percentages). Results will be analyzed on an item-by-item or variable-by-variable basis. These descriptive statistics will allow for the assessment of how rates vary for each of the items evaluated. No formal hypothesis testing will be conducted. The risk minimisation activities will be considered successful if a majority of psychatrists participating in the survey are aware of and prescribe Strattera in accordance with the cardiovascular/cerebrovascular contraindications, warnings and precautions and the recommendation to monitor blood pressure and heart rate in all patients at baseline and during treatment with Strattera.

Documents

Study results

B028 PASS FSR.pdf(1.84 MB)

Study, other information

B028 RMiP PASS Protocol_2.pdf(211.6 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

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

Unknown