Physician Survey to Reassess Effectiveness of Strattera Risk Minimisation Activities

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/8929

EU PAS number

EUPAS4577

Study ID

8929

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Netherlands
- ☐ Sweden

United Kingdom

Study description

This is a survey to re-assess the effectiveness of the atomoxetine risk minimisation activities among physicians who prescribe Strattera and/or monitor patients being treated with Strattera.

Study status

Finalised

Research institutions and networks

Institutions

GfK Health

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Institution

Contact details

Study institution contact

Nicole Kellier

Study contact

nkellier@lilly.com

Primary lead investigator

Nicole Kellier

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 26/04/2013

Study start date
Planned: 15/09/2013

Actual: 13/09/2013

Data analysis start date
Planned: 01/12/2013

Actual: 01/12/2013

Date of final study report
Planned: 28/03/2014

Actual: 27/03/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

RMiP PASS protocol_p1.pdf(124.46 KB)

RMiP PASS protocol_p1_mod.pdf(180.31 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Not applicable

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

Re-assessment of the effectiveness of the atomoxetine risk minimisation activities among physicians who prescribe Strattera and/or monitor patients being treated with Strattera. The goal of these activities is to inform HCPs of the cardiovascular or cerebrovascular disorder contraindication and SPC recommendation to monitor BP and HR in all patients at baseline and during treatment with Strattera

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06BA09) atomoxetine

atomoxetine

Population studied

Short description of the study population

Physicians (Peadiatricians, Child/Adolescent Psychiatrists or other NonPeadiatricians and GPs) who prescribe Strattera and/or monitor patients treated with Strattera

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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

550

Study design details

Outcomes

The risk minimisation activities assessed by this survey include sustained knowledge and awareness of the risk messages, The survey will also include an assessment of awareness and adherence to the changes in the SmPC requirements specific to cardiovascular risks and monitoring

Data analysis plan

Data analyses will be descriptive and will entail tabular displays of mean values and the frequency distribution of item responses.

Documents

Study results

B024 PASS.pdf(1.87 MB)

Study, other information

RMiP PASS protocol_p2.pdf(276.74 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

No