The Risk of Dystonia among Children and Adolescents Treated with Atomoxetine within the Truven MarketScan Database (B4Z-MC-B031)

First published: 24/03/2016

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11221

Study ID

23712

DARWIN EU® study

No

Study countries

United States

Study description

The proposed study is a retrospective cohort study using secondary data from the Truven Health Analytics MarketScan database. The primary objective is to evaluate the incidence and risk of dystonia among atomoxetine treated patients between 6 to 17 years of age relative to a propensity score matched cohort of stimulant treated patients. This objective will be attained by estimating the hazard ratio (HR) from a Cox proportional hazards regression model.

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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
Actual: 06/01/2016

Study start date
Actual: 11/01/2016

Date of final study report
Planned: 30/09/2016

Actual: 06/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B031 PASS(1.0).pdf (565.2 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to evaluate the incidence and risk of dystonia among atomoxetine treated patients between 6 to 17 years of age relative to a propensity score matched cohort of stimulant treated patients.

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

Children and adolescents (6-17 years of age) treated with atomoxetine with at least 6 months (180 days) of continuous enrolment in the Truven Health Analytics MarketScan database prior to index date.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

337182

Study design details

Outcomes

Dystonia (as indicated by presence of ICD-9-CM codes 333.7, 333.72, 333.79, 333.81, 333.83, 333.84, or 333.89).

Data analysis plan

The primary analysis will be a comparison of the risk of dystonia in patients initiating atomoxetine relative to a propensity score matched cohort of individuals initiating a stimulant. This comparison will be carried out using Cox proportional hazards regression. An overview of the analysis strategy is outlined below:-Estimate propensity score for atomoxetine initiation for each patient in the atomoxetine and stimulant cohorts-Use Greedy 1:1 matching algorithm to form propensity score matched sample-Assess balance between cohorts across all baseline covariates using standardised differences-Revise and finalize propensity score as needed-Estimate the hazard ratio (HR) (with 95% confidence interval) of dystonia associated with atomoxetine using a Cox proportional hazards regression model-Perform sensitivity analyses-Assess generalisability by summarising population characteristics and outcomes for patients included and excluded by matching process

Documents

Study results

LY139603-B4Z-MC-B031 PASS Final Study Report Version 2.pdf.pdf (3.17 MB)

Study publications

Meyers KJ, Upadhyaya HP, et al. Evaluation of dystonia in children and adolesce...

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), other

Truven Health Analytics MarketScan®

Data sources (types)

Administrative healthcare records (e.g., claims)

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