

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

PURI

<https://redirect.ema.europa.eu/resource/23712>

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

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

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