Stress Urinary Incontinence and Suicidality Seen in the United Kingdom General Practice Research Database (F1J-MC-B056)

First published: 02/08/2017

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS20247

Study ID

21190

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This study investigated the association between stress urinary incontinence (SUI) and suicidality:Primary Objective: To assess the association between suicide attempts (both non-fatal and completed) and receipt of duloxetine treatment in women with SUI compared to SUI women without duloxetine treatment, accounting for important demographic and medical history covariates.Secondary Objective: To study the association between suicidal ideation and duloxetine by comparing women with SUI who received duloxetine and women with SUI who did not receive duloxetine, accounting for important demographic and medical history covariates.Exploratory Objectives: To evaluate the association between suicidality-related outcomes and SUI case status or not, accounting for important demographic and medical history covariates.

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hu Li

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/11/2015

Actual: 11/11/2015

Study start date

Planned: 01/12/2017

Actual: 27/01/2016

Data analysis start date

Planned: 01/10/2016

Actual: 12/05/2017

Date of final study report

Planned: 31/03/2017

Actual: 01/09/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

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:

Disease /health condition

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 the study is to assess the association between suicide attempts (both non-fatal and completed) and receipt of duloxetine treatment in women with SUI compared to SUI women without duloxetine treatment, accounting for important demographic and medical history covariates.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ARICLAIM

CYMBALTA

YENTREVE

Medicinal product name, other

Xeristar

Medical condition to be studied

Completed suicide

Suicide attempt

Suicidal ideation

Population studied

Short description of the study population

Adult women who were registered in active medical practices with CPRD quality-verified records with a minimum follow up-time of 1 year.

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

5000

Study design details

Outcomes

suicide attempts (both non-fatal and completed), suicidal ideation

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Data analysis plan

For the primary comparison of suicide attempt (non-fatal attempt & complete suicide) rates between SUI patients exposed vs SUI patients not exposed to duloxetine, a Cox proportional hazard model will be used to estimate adjust HR along with 95% CI. Sensitivity analysis 1)apply different grace periods other than 30 d & ITT analysis, 2)assess the impact of various definitions of suicidal

outcomes. Post Hoc Analyses: this analysis will use propensity score stratification, as it maximizes the use of full sample size comparing to some other methods, ie propensity score matching. A pooled estimate of the variance of the estimated treatment effect can be obtained by pooling the variances of the stratum-specific treatment effects. PostHoc Analyses Using Additional Comparator Groups: like the main analysis, patients with baseline duloxetine exposure will be excluded, & patients with other antidepressants exposure at baseline & considered in the propensity score model.

Documents

Study results

B056_PASS CSR.pdf (1.5 MB)

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)

Clinical Practice Research Datalink

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

Unknown