# 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





### Administrative details

**Study description** 

EU PAS number
EUPAS20247
Study ID
21190
DARWIN EU® study
No
Study countries
United Kingdom

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** 

li\_hu\_hl@lilly.com

#### **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

#### Name of medicine

**ARICLAIM** 

**CYMBALTA** 

YENTREVE

#### Name of medicine, other

Xeristar

#### Medical condition to be studied

Completed suicide

Suicide attempt

## 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

#### 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)

## Use of a Common Data Model (CDM)

CDM	man	nina
CDII	map	פיייקי

No

## Data quality specifications

#### **Check conformance**

Unknown

#### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

### Data characterisation

#### **Data characterisation conducted**

Unknown