Hepatic Outcomes Among Adults Taking Duloxetine in a US Health Care Claims Database (F1J-MC-B037)

First published: 01/10/2014

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7584

Study ID

20329

DARWIN EU® study

No

Study countries

United States

Study description

We conducted a retrospective matched cohort study toevaluate the association of clinically significant hepaticinjury and exposure to duloxetine, with specificdefinitional and methodological enhancements to focuson potential drug-related associations. The primarystudy objective was to estimate the absolute and relativeincidence of clinically significant hepatic events(hepatic-related death, liver failure, other clinicallysignificant liver injury, hepatic-related death and liverfailure combined, all clinically significant hepatic injurycategories combined) among patients with depressionwho initiated duloxetine relative to each of 3 propensityscore-matched comparison cohorts: patients withdepression who initiated venlafaxine, patients withdepression who initiated SSRIs, and patients with adiagnosis of depression who did not receive treatment.Secondary objectives addressed a range of potentialalternative explanations for the observed results (e.g.,residual confounding).

Study status

Finalised

Research institutions and networks

Institutions

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Outdated | Other | ENCePP partner

Contact details

Study institution contact

Hu Li li_hu_hl@lilly.com

Study contact

li_hu_hl@lilly.com

Primary lead investigator

Hu Li

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2010

Actual: 07/12/2012

Study start date

Planned: 01/04/2010

Actual: 07/12/2012

Date of final study report

Planned: 01/05/2013

Actual: 20/09/2013

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:

to estimate the absolute and relative incidence of clinically significanthepatic events among patients with depression who initiated duloxetine relative to each of 3 propensity score-matched comparison cohorts.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06AX21) duloxetine

duloxetine

Medical condition to be studied

Drug-induced liver injury

Population studied

Short description of the study population

Adults (18+ years of age) who: initiated at least one study antidepressant (duloxetine, venlafaxine, or SSRI) between 01 August 2004 and 31 September

2010, or who had a diagnosis of depression without an antidepressant medication; were members of a commercial health plan that allows access to medical records for research purposes, with complete medical coverage and pharmacy benefits; met 12 months prior continuous enrollment criteria, and had a claim for diagnosis of depression during the 12-month baseline period.

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)

Special population of interest

Hepatic impaired

Estimated number of subjects

30844

Study design details

Outcomes

Clinically significant hepatic injury (hepatic-related death, liverfailure, other clinically significant hepatic injury,hepatic-related death or liver failure combined, and allclinically significant hepatic categories combined). non-serious asymptomatic hepatic enzyme elevation

Data analysis plan

We matched duloxetine initiators to each of the 3 comparator cohorts (venlafaxine, SSRI, untreated) using a multivariable technique (propensity score

analysis and matching) that can achieve a high degree of balance between comparison groups. Incidence rates were calculated as the number of cases divided by the relevant person-time. We also estimated 95% confidenceintervals (CIs) of the IRs for the duloxetine initiator and comparator cohorts. Rate ratios (RR) and associated 95% CIs were estimated for duloxetine initiators compared with each of the 3 propensity score-matched comparator cohorts.

Documents

Study results

Duloxetine_Revised Final Report_Case Addendeum (Editorial Revisions) Revised 20 Sep 2013.pdf (1.65 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), other

Optumum Insight, United States

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