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

PURI

https://redirect.ema.europa.eu/resource/20329

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 | Other | ENCePP partner

Contact details

Study institution contact

Hu Li

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

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