An Observational Study of Upper Gastrointestinal Tract (UGIT) Bleeding Events in Patients Taking Duloxetine and NSAIDs (F1J-MC-B040)

First published: 01/10/2014

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS7588

Study ID

20325

DARWIN EU® study

No

Study countries

United States

Study description

This study was a retrospective case-control analysis. The interaction between duloxetine and prescribed NSAIDs is described as the odds ratio (OR) for risk of UGI bleed where there is exposure to both duloxetine and prescription nonselective NSAIDs, COX-2 selectiveNSAIDs or prescription aspirin. Multivariable analysis using logistic regression provided adjusted OR and 95% confidence intervals (CIs). The primary endpoint of whether concomitant use of duloxetine and Rx NSAIDs is associated with a synergistic effect on the risk of UGIbleed was conducted with a relative excess risk due to interaction (RERI) calculation. The risk of UGI bleeding associated with duloxetine exposure was assessed via multivariable analysis, and the severity ofUGI bleeding cases across all study populations was described. The interaction between duloxetine and prescription NSAIDs (nonselective NSAIDs, COX-2 selective NSAIDs, and prescription aspirin combined)as well as over the counter (OTC) NSAIDs was conducted as sensitivity analyses.

Study status

Finalised

Research institutions and networks

Institutions

Clinical, Regulatory and Safety, Cerner Enviza

Germany

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Institution | Non-Pharmaceutical company | ENCePP partner

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: 10/01/2013

Actual: 14/01/2013

Study start date

Planned: 10/01/2013

Actual: 14/01/2013

Date of final study report

Planned: 28/06/2013

Actual: 28/06/2013

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 examine whether concomitant use of duloxetine and prescription NSAIDs is associated with a synergistic effect on the risk of UGI bleedingSecondary objective: To study the risk of UGI bleeding associated with duloxetine exposure without concomitant NSAIDs Secondary objective: To characterize the severity of UGI bleeding cases across all study populations.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06AX21) duloxetine

duloxetine

Medical condition to be studied

Upper gastrointestinal haemorrhage

Population studied

Short description of the study population

All patients in Truven Health Analytics Marketscan (THAM) (Commercial Claims and Encounter and Medicare Supplemental) database from 1 January, 2007 to 31 December, 2011 with an inpatient admission with a length of stay >24 hours during the intake period of 1 January, 2008 to 30 September, 2011 who were ≥18 years of age at the time of admission, and who had at least 1 year of continuous eligibility prior to and 3 months after their admission date.

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

33.571

Study design details

Outcomes

Upper GI bleeding

Data analysis plan

Truven Health Analytics Marketscan database was examined for hospital admissions of adult patients indexed from 1 January 2007 to 31 December 2011. Cases were patients with UGI hemorrhage or peptic ulcer disease. Controls were randomly selected from the remainingadmissions to match 10:1 with cases based on age, gender, and admission date. Prescription medication exposure groups of interest were: 1) no exposure to duloxetine, NSAIDs or aspirin, 2) duloxetine only, 3) NSAIDs or aspirin only, 4) duloxetine + NSAIDs or

aspirin. Logistic regression and Relative Excess Risk due to Interaction (RERI) was utilized to estimate any increased risk of UGI bleeding for patients prescribed these medications across these groups.

Documents

Study results

Duloxetine EMA Final_v2_HL_encepp.pdf (1.05 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

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

Unknown