Risk of Upper Gastrointestinal Complications in Users of Nonsteroidal Anti-inflammatory Drugs

First published: 21/10/2011
Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/5088

EU PAS number
EUPAS2225

Study ID
5088

DARWIN EU® study
No

Study countries
Italy

Study description
Retrospective cohort study and nested case-control analysis to evaluate the risk of upper gastrointestinal complications (UGIC) in a cohort of patients receiving NSAIDs between 2001-2008 in the Italian region of Friuli Venezia Giulia (FVG). The study was conducted by a research team from RTI Health Solutions, the Institute of Hygiene and Clinical Epidemiology of the University of Udine and University Hospital of Udine, and the Direzione Centrale della Salute, Integrazione Socio Sanitaria e Politiche Sociali, Udine. The study was based on information from the FVG Regional Health Services Databases and hospital medical charts for the validation of cases of UGIC. The objectives of the study were to (1) estimate the risk of UGIC associated with the use of nimesulide and other individual NSAIDs, (2) evaluate the effect of dose and duration of use of individual NSAIDs and the

role of potential risk factors for UGIC, and (3) describe the characteristics of nimesulide users over time.

Study status
Finalised

Research institution and networks

Institutions

RTI Health Solutions (RTI-HS)

France
Spain
Sweden
United Kingdom
United Kingdom (Northern Ireland)
United States
First published: 21/04/2010
Last updated
19/02/2024

Institution | Not-for-profit | ENCePP partner

Istituto di Igiene ed Epidemiologia, DSMB Universita' di Udine

Italy
First published: 03/10/2011
Last updated
17/10/2017

Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Susana Perez-Gutthann
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
20/10/2009

Study start date
Planned:
15/12/2009
Actual:
08/02/2010

Data analysis start date
Planned:
01/05/2010
Actual:
01/06/2010

Date of interim report, if expected
Actual:
23/03/2011

Date of final study report
Planned:
14/02/2011
Actual:
01/07/2011

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Helsinn Healthcare, S.A.

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study topic:
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Disease epidemiology
Drug utilisation

Data collection methods:
Secondary data collection

Main study objective:
The objectives of the study are to (1) estimate the risk of UGIC associated with the use of nimesulide and other individual NSAIDs, (2) evaluate the effect of dose and duration of use of individual NSAIDs and the role of potential risk factors for UGIC, and (3) describe the characteristics of nimesulide users over time.

Study Design

Non-interventional study design
Case-control
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(M01A) ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

Population studied

Short description of the study population
All residents in the Friuli-Venezia Giulia, Italy (FVG) region with at least 1 year of permanent residence who are prescribed nimesulide or any other NSAID between January 1, 2001, and December 31, 2008

Age groups
Children (2 to < 12 years)
Adolescents (12 to < 18 years)
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
588827

Study design details

Outcomes
Upper gastrointestinal bleeding, perforation, obstruction.

Data analysis plan
Crude age- and sex-specific incidence rates and 95% confidence intervals of UGIC were estimated for current use of NSAIDs and nonuse of NSAIDs. Incidence rates were stratified by history of peptic ulcer and calendar year. The nested case-control analysis was the main analysis of the study. All confirmed cases of UGIC from the study cohort were included in the analysis. Density-based sampling was used to select 10 controls for each case. We used conditional logistic regression to estimate crude and adjusted odds ratios for the risk of UGIC during the periods of exposure to each individual NSAID with the risk during nonuse of NSAIDs. The model was built manually based on the impact on the effect estimate of NSAIDs and the inclusion of factors associated with increased risk of UGIC, general medical frailty, or with potential selective prescribing of NSAIDs. Effect measure modification was assessed for age, sex, and concurrent use of aspirin, anticoagulants, and oral corticosteroids.

Documents

Study publications
Castellsague J, Pisa P, Rosolen V, Riera-Guardia N, Giangreco M, Clagnan E, Tos…
Pisa P, Castellsague J, Rosolen V, Riera-Guardia N, Giangreco M, Drigo D, Perez…
Castellsague J, Pisa F, Rosolen V, Drigo D, Riera-Guardia N, Giangreco M, Clagn…
Pisa F, Castellsague J, Drigo D, Riera-Guardia N, Giangreco M, Rosolen V, Clagn…
Pisa F, Drigo D, Riera-Guardia N, Castellsague J, Rosolen V, Clagnan E, Tosolin…

Data management

Data sources

Data sources (types)
Administrative data (e.g. claims)
Drug dispensing/prescription data
Other

Data sources (types), other
Hospital medical records

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
No