

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

**First published:** 21/10/2011

**Last updated:** 12/12/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS2225

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### Study ID

5088

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### DARWIN EU® study

No

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### Study countries

 Italy

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### 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.

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## Study status

Finalised

## Research institutions 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:** 13/03/2025

**Institution**

**Not-for-profit**

**ENCEPP partner**

Istituto di Igiene ed Epidemiologia, DSMB Università  
di Udine

 Italy

**First published:** 03/10/2011

**Last updated:** 17/10/2017

**Institution**

**Outdated**

**Educational Institution**

**ENCEPP partner**

## Contact details

### Study institution contact

Susana Perez-Gutthann [sperez@rti.org](mailto:sperez@rti.org)

**Study contact**

[sperez@rti.org](mailto:sperez@rti.org)

### Primary lead investigator

Susana Perez-Gutthann

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Actual: 20/10/2009

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## **Study start date**

Planned: 15/12/2009

Actual: 08/02/2010

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## **Data analysis start date**

Planned: 01/05/2010

Actual: 01/06/2010

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## **Date of interim report, if expected**

Actual: 23/03/2011

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## **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

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

Study type

Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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  
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

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### **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)
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### **Estimated number of subjects**

588827

## Study design details

### **Outcomes**

Upper gastrointestinal bleeding, perforation, obstruction.

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### **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...](#)

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## 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 sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

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## **Data sources (types), other**

Hospital medical records

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

# Data quality specifications

## **Check conformance**

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No