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

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# 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.

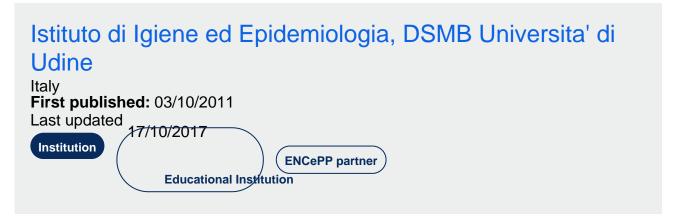
## Study status

Finalised

# Research institution and networks

## Institutions





# Contact details

Study institution contact
Susana Perez-Gutthann
Study contact

sperez@rti.org

## 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 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