# Incidence of Gastrointestinal Perforation in Users of ACTEMRA® (Tocilizumab), Rituxan® (Rituximab), Abatacept and Anti-Tumor Necrosis Factor Alpha Agents

**First published:** 23/12/2016

**Last updated:** 14/03/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS16960

**Study ID**

103373

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

The current study seeks to compare the incidence of GI perforation among users of abatacept, Rituxan®, anti-TNF alpha agents and Actemra®, an interleukin-6 (IL-6) receptor inhibitor indicated for the treatment of moderately to severely active rheumatoid arthritis in adult patients who have had an inadequate response to one or more biologic therapies.

**Study status**

Finalised

## Contact details

**Study institution contact**

Khaled Sarsour global.clinical_trial_registry@roche.com

**Study contact**

global.clinical_trial_registry@roche.com

**Primary lead investigator**

Khaled Sarsour

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 01/02/2013

**Study start date**

Actual: 01/02/2013

**Data analysis start date**

Actual: 01/02/2013

**Date of final study report**
Actual: 22/05/2013

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Roche

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

## Other study registration identification numbers and links

GA29300

# 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:**

The main and primary objective of this study was to compare the incidence of GI perforation amongst new users of Actemra, abatacept, Rituxan and individual anti-TNF alpha agents in RA patients who have previously discontinued at least one biologic agent.

## Study Design

**Non-interventional study design**

Cohort

Other

---

**Non-interventional study design, other**

Retrospective study

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

TOCILIZUMAB

**Medical condition to be studied**

Gastrointestinal perforation

# Population studied

**Short description of the study population**

The study population involved patients treated with tocilizumab for gastrointestinal perforation identified from the US healthcare claims databases (Truven Health MarketScan Commercial Claims and Encounters and Medicare Supplemental and Coordination of Benefits).

**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**

Other

**Special population of interest, other**

Patients with rheumatoid arthritis

**Estimated number of subjects**

0

# Study design details

**Outcomes**

The main and primary objective of this study was to compare the incidence of GI perforation amongst new users of Actemra, abatacept, Rituxan and individual anti-TNF alpha agents in RA patients who have previously discontinued at least one biologic agent. Secondary objectives were twofold: to identify risk factors associated with GI perforation as well as to identify differences in patients treated with Actemra, abatacept, Rituxan or another anti-TNF agent after discontinuation of a previous biologic agent.

---

**Data analysis plan**

Descriptive results are presented in tabular format. Basic analyses included descriptive profiles of all independent and dependent variables. Categorical variables are summarized in frequency tables. Continuous and other numeric variables are summarized by presenting the number of observations, mean, standard deviation, and median. Statistical tests of significance for differences in these distributions were carried out. Chi-square tests were used to assess the statistical significance of categorical variables, t-tests and ANOVA were used for continuous variables. Standard errors were adjusted for the lack of independence across cohorts and within the anti-TNF cohort.

## Documents

**Study publications**

Monemi, S., Berber, E., Sarsour, K. et al. Incidence of Gastrointestinal Perfor…

---

# 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

# 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