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

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Study | Finalised

Administrative details

EU PAS number

EUPAS16143

Study ID

28348

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, rituximab, the class of 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 tumor necrosis factor (TNF) antagonist therapies. For the purpose of this study anti-TNF alpha agents are Infliximab, Etanercept, Adalimumab, Certolizumab, and Golimumab

Study status

Finalised

Research institutions and networks

Institutions

NA

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Khaled Sarsour

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 10/04/2015

Study start date
Actual: 15/06/2015

Date of final study report
Actual: 08/10/2015

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)?

EU RMP category 3 (required)

Other study registration identification numbers and links

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 primary objective of this study is to compare the incidence of GI perforation amongst new users of tocilizumab, abatacept, and individual and aggregate anti-TNF alpha agents in RA patients previously exposed to at least one anti-TNF alpha agent.

Study Design

Non-interventional study design

Cohort

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

New users of tocilizumab, abatacept, and individual and aggregate anti-TNF alpha agents in rheumatoid arthritis patients previously exposed to at least one anti-TNF alpha agent.

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

Immunocompromised

Estimated number of subjects

0

Study design details

Outcomes

The primary objective of this study is to compare the incidence of GI perforation amongst new users of tocilizumab, abatacept, and individual and aggregate anti-TNF alpha agents in RA patients previously exposed to at least one anti-TNF alpha agent. To describe demographic, clinical and treatment characteristics of the study cohort and factors associated with increased risk of GI perforation.

Data analysis plan

Basic analyses will include descriptive profiles of all independent and dependent variables. Categorical variables will be summarized in frequency tables. Continuous and other numeric variables will be summarized by presenting the number of observations, mean, standard deviation, and median. Statistical tests of significance for differences in these distributions will be carried out. Chi-square tests will be used to assess the statistical significance of categorical variables, t-tests and ANOVA will be used for continuous variables.

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)

Disease registry

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

Unknown