

Rates for Anaphylaxis for Patients with Rheumatoid Arthritis Treated with Tocilizumab or Other Biologics: An Analysis Based on Health Claims Data

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Study

Finalised

Administrative details

EU PAS number

EUPAS18844

Study ID

18901

DARWIN EU® study

No

Study countries

☐ United States

Study status

Finalised

Research institutions and networks

Institutions

F. Hoffmann-La Roche

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Institution

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: 15/11/2014

Study start date

Actual: 01/12/2014

Data analysis start date

Actual: 01/12/2014

Date of final study report

Actual: 03/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche Ltd

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

GA29837

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:

Incidence rate of anaphylaxis and fatal anaphylaxis

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective database study

Study drug and medical condition

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

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

Patients with rheumatoid arthritis treated with Tocilizumab or other biologics.

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

Rheumatoid arthritis patients

Estimated number of subjects

0

Study design details

Outcomes

- Incidence rate of anaphylaxis and fatal anaphylaxis- Incidence rate of fatal anaphylaxis

Data analysis plan

For IV drugs, anaphylaxis rates will be calculated for events occurring within 7 days, 14 days and 30 days following anaphylaxis. The primary analysis is that of events occurring within 7 days of drug infusion. The rest are sensitivity analyses. Fatal Anaphylaxis rates will be calculated for events occurring within 7 days, 14 days and 30 days following anaphylaxis. The primary analysis will be for fatal events occurring within 7 days of anaphylaxis. Fatal events occurring with 14 and 30 days will be conducted as sensitivity analyses. Descriptive statistics including patient numbers and proportions will be calculated for all study cohorts by patient age, gender, insurance plan, and region. Duration of enrollment (i.e. database history) will be calculated from enrollment date to index date and from index date to disenrollment or database cutoff date. Means with standard deviation (SD) and medians with interquartile range (IQR) will be presented where appropriate.

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 registry

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