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

PURI
https://redirect.ema.europa.eu/resource/18901

EU PAS number
EUPAS18844

Study ID
18901

DARWIN EU® study
No

Study countries
United States

Study status
Finalised

Research institution 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 data collection

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
TOCILIZUMAB

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

Data sources

Data sources (types)
Administrative data (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