A SECONDARY DATA USE STUDY OF LONG TERM SAFETY OF TOCILIZUMAB BASED ON ANTI RHEUMATIC THERAPY IN SWEDEN (ARTIS) PATIENT REGISTRY

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Study Finalised

Administrative details

EU PAS number

EUPAS23708

Study ID

32844

DARWIN EU® study

No

Study countries

Sweden

Study description

This Retrospective Secondary Data Use study is nested within the Anti-Rheumatic Therapy in Sweden (ARTIS) patient registry in Sweden to study the long term safety of tocilizumab in routine clinical practice.

Study status

Finalised

Contact details

Study institution contact

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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: 06/04/2009

Study start date

Actual: 28/04/2009

Date of final study report

Planned: 31/03/2019

Actual: 19/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

WA22480_ Protocol.pdf (305.13 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

WA22480

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:

To provide long term safety evaluation of Tocilizumab (TCZ) and descriptive 6-monthly reports of incidence rates of safety events of interest in TCZ patients.To conduct an adjusted multivariate analysis of data comparing risk of seriousadverse events in TCZ treated patients as compared with multiple RA biologic and non-biologic treated patients and a general population comparison cohorts

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

Rheumatoid arthritis

Population studied

Short description of the study population

Rheumatoid arthritis patients treated with tocilizumab in Sweden.

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

Events in 1) TCZ recipients will be compared with those in patients with 2) anti-TNF therapy and 3) standard DMARD.For the above groups, incidence rates of the following primary endpoints will be determined:• Serious infection requiring hospitalization • Malignancy • Myocardial infarction • Stroke leading to hospitalization • Death • GI perforations • Serious hepatic events • Tuberculosis, Other outcomes, occurrence of the following events will be assessed from the adverse events reporting, no comparator data are, however, available for these events:• occurrence of serious hypersensitivity reactions (depending on data availability)• Demyelinating disorders• Lower gastrointestinal ulcer/bleeding/perforation• Aplastic anaemia/pancytopenia• Lymphoproliferative tumour

Data analysis plan

Descriptive data will be provided on incidence rates of safety events of interestand a final adjusted analysis that compares risk of safety eventsin tocilizumab treated group with multiple RA and generalpopulation cohorts. Discrete or continuous variables will be summarized in terms of mean, standard deviation, median, and first and third quartile. Categorical variables will be summarized in terms of frequencies of categories. Treatment groups will be compared using Kruskal–Wallis tests for discrete or continuous variables and Fisher’s exact tests for categorical variables.

Documents

Study results

ARTIS Comparative Safety Report RoActemra_20181220.pdf (1.84 MB)

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)

Disease 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

No