Risk of Cardiovascular Events in Patients Using Tocilizumab as Compared With Other Biologics in Multiple Large Healthcare Databases (EUPAS16133)

First published: 18/11/2016

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16133

Study ID

50684

DARWIN EU® study

No

Study countries

United States

Study description

This retrospective cohort study will analyze data from multiple large U.S. health insurance claims databases to compare use of tocilizumab to other biologic disease modifying anti-rheumatic drugs (DMARDs) in real world patients with RA. Using the date of dispensing as the index date, the analysis will compute the time to first event for several cardiovascular outcomes.

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: 12/08/2015

Study start date

Actual: 02/06/2016

Data analysis start date

Actual: 02/06/2016

Date of final study report
Planned: 15/01/2018

Actual: 03/12/2018

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

GA30048

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 compare the cardiovascular risk in RA patients treated with tocilizumab versus RA patients treated with other biologic disease modifying anti-rheumatic drugs (DMARDs) in real world settings.

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

Rheumatoid arthritis

Population studied

Short description of the study population

The study focused on risk of cardiovascular events in patients with rheumatoid arthritis received tocilizumab as compared with other biologics identified from the large U.S. health insurance claims databases.

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

76.000

Study design details

Outcomes

Time to First Event of Myocardial Infarction (MI) or Stroke with Tocilizumab Versus Tumor Necrosis Factor Inhibitor, - Time to First Event of MI or Stroke with Tocilizumab Versus Non-TNFi Therapies - Time to Hospitalization for Coronary Revascularization Procedure - Time to Hospitalization for Acute Coronary Syndrome (ACS) - Time to First Event of MI, Stroke, Coronary Revascularization Procedure, or ACS - Time to Heart Failure (HF) Requiring Hospitalization - Time to All-Cause Death

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Data analysis plan

For each cohort, two analysis sets will be defined and applied to the proposed analyses as specified: the as treated (AT) and the intention to treat (ITT). Each analysis set is defined below: •Primary analysis – AT: Patients are included from the index date (drug exposure) until the earliest date of death, disenrollment, outcome development, end of the database time period, or discontinuation of the given drug. The last drug available date will be defined as the last drug dispensing date + days of supply for subcutaneous or oral agents. For intravenously administrated drugs, we will define the last drug available date as the drug infusion date + 30 days for abatacept and tocilizumab, and 56 days for golimumab and infliximab. •Secondary analysis – ITT: Patients are included from the index date until the earliest date of 180 pr 365 days of followup, death, disenrollment, or outcome development. First defined drug exposure will be carried forward.

Documents

Study publications

Kim SC, Solomon DH, Rogers JR, Gale S, Klearman M, Sarsour K, Schneeweiss S. Ca…

Kim SC, Solomon DH, Rogers JR, Gale S, Klearman M, Sarsour K, Schneeweiss S. No...

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

Drug registry

Electronic healthcare records (EHR)

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