COMPARATIVE SAFETY OF TOCILIZUMAB VERSUS OTHER BIOLOGIC DMARDS IN PATIENTS WITH RHEUMATOID ARTHRITIS: A LARGE MULTI-DATABASE COHORT STUDY

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Study | Finalised

Administrative details

EU PAS number

EUPAS19948

Study ID

29792

DARWIN EU® study

No

Study countries

Germany

Study description

Because the majority of previous safety studies on TCZ did not include a direct comparison to a different biologic drug, a large, high-quality population-representative evidence on comparative safety of TCZ versus other biologics for RA on the risk of serious infection and malignancy is needed.This study will be performed within multiple large healthcare administrative claims databases based in the US. The data sources are Medicare (2008-2015), IMS PharMetrics (2006-2015) and Truven MarketScan (2009-2015) databases.

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

Sara Gale

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 04/08/2017

Actual: 02/08/2017

Study start date
Planned: 15/08/2017

Actual: 14/09/2017

Date of final study report
Planned: 12/06/2018

Actual: 17/10/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

EUPAS19948_ ACTEMRA_redacted protocol.pdf (1.01 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

MA39102

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 main objective of this NIS is to compare rates of different safety events including malignancy excluding non-melanoma skin cancer NMSC, serious bacterial or viral infection, opportunistic infection and herpes zoster, between tocilizumab and tumor necrosis factor-alpha inhibitors.

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

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

Immunocompromised

Estimated number of subjects

0

Study design details

Outcomes

- To examine the rate of malignancy excluding NMSC in RA patients starting TCZ versus TNFi.- To investigate the rate of serious bacterial, viral or opportunistic infection in RA patients starting TCZ versus TNFi

Data analysis plan

The primary analysis will be propensity score (PS) matched time to event safety analyses for each outcome comparing risk in TCZ compared with a specified comparator. Analyses will be performed per each of the three databases separately and then, if deemed appropriate, pooled for a weighted hazard ratio. Additional analyses include descriptive statistics, incorporation of time-varying confounders, and pre-specified sensitivity analyses to evaluate the robustness of some of the parameter assumptions .

Documents

Study results

MA39102_abstract_final.pdf (107.21 KB)

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)

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