Incidence of Interstitial Lung Disease (ILD) in Users of ACTEMRA® (Tocilizumab), Rituxan® (Rituximab), Abatacept and Anti-Tumor Necrosis Factor Alpha Agents

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Study | Finalised

Administrative details

EU PAS number

EUPAS16482

Study ID

103379

DARWIN EU® study

No

Study countries

United States

Study description

The current study seeks to compare the incidence of interstitial lung disease among users of abatacept, Rituxan®, individual and the class of anti-TNF alpha agents and Actemra®, an interleukin-6 (IL-6) receptor inhibitor indicated for the treatment of moderately to severely active rheumatoid arthritis in adult patients who have had an inadequate response to one or more biologic therapies.

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: 01/02/2013

Study start date

Actual: 28/02/2013

Data analysis start date
Actual: 28/02/2013

Date of final study report
Actual: 27/09/2013

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)?

Not applicable

Other study registration identification numbers and links

GA29301

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

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 primary and main objective of this study is to compare the incidence of ILD amongst new users of Actemra®, abatacept, Rituxan® and individual anti-TNF alpha agents in RA patients previously exposed to at least one previous biologic agent.

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

RITUXIMAB

ABATACEPT

CERTOLIZUMAB PEGOL

ETANERCEPT

ADALIMUMAB

INFLIXIMAB

GOLIMUMAB

Medical condition to be studied

Interstitial lung disease

Population studied

Short description of the study population

The study population involved patients with rheumatoid arthritis aged 18 years or older treated with abatacept, rituximab, tocilizumab, or anti-TNF after having discontinued a different biologic agent identified from MarketScan databases between 1 January 2010 and 30 June 2012.

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

0

Study design details

Outcomes

The primary and main objective of this study is to compare the incidence of ILD amongst new users of Actemra®, abatacept, Rituxan® and individual anti-TNF alpha agents in RA patients previously exposed to at least one previous biologic agent. Secondary objectives include comparing the frequency of ILD complications in the same patient population and the identification of risk factors associated with either incident ILD or ILD complications.

Data analysis plan

Basic analyses will include descriptive profiles of all independent and dependent variables. Categorical variables will be summarized in frequency tables. Continuous and other numeric variables will be summarized by presenting the number of observations, mean, standard deviation, and median. Statistical tests of significance for differences in these distributions will be carried out. Chi-square tests will be used to assess the statistical significance of categorical variables, t-tests and ANOVA will be used for continuous variables.

Documents

Study publications

Curtis JR, Sarsour K, Napalkov P, Costa LA, Schulman KL. Incidence and complica…

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)

Drug dispensing/prescription data

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