Multinational, multicentre, non-interventional study, in patients with rheumatoid arthritis (RA) treated with tocilizumab (ACT-UP)

First published: 29/05/2015

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Study Ongoing

Administrative details

EU PAS number

EUPAS9834

Study ID

17512

DARWIN EU® study

No

Study countries

Costa Rica

Dominican Republic

Guatemala

Panama

Study description

This multicenter, observational study will evaluate the use and efficacy of RoActemra/Actemra (tocilizumab) in routine clinical practice in patients with moderate to severe rheumatoid arthritis. Eligible patients initiated on RoActemra/Actemra treatment in accordance with the local label will be followed for 6 months.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

virginia.cozzi@roche.com

Primary lead investigator

Virginia Cozzi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/10/2013

Study start date

Actual: 08/10/2013

Data analysis start date
Actual: 02/06/2014

Date of final study report
Planned: 30/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche Central America and the Caribbean

Study protocol

ML28747_Protocol Amendment History v.3 final version English.pdf (406.46 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To observe, in routine clinical practice, patterns of use of tocilizumab in patients with RA, for continuity of treatment and adherence to the recommendations adopted in the instructions or data sheet.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Actemra

Study drug International non-proprietary name (INN) or common name

TOCILIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC07) tocilizumab

tocilizumab

Medical condition to be studied

Rheumatoid arthritis

Population studied

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)

Estimated number of subjects

169

Study design details

Outcomes

To observe, in routine clinical practice, patterns of use of tocilizumab in patients with RA, for continuity of treatment and adherence to the recommendations adopted in the instructions or data sheet. Observe the behavior of hemoglobin at weeks 0 and 24• Observe the rates and reasons for the changes in the doses oftocilizumab•To observe the demographics and characteristics of RA when starting treatment with tocilizumab•To observe the efficacy and safety of treatment in clinical practice

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Data analysis plan

The analysis in this study primarily used descriptive statistical methods. In addition, it will use modeling and exploratory statistical analyses to highlight interesting aspects of the data.Unless otherwise specified, all tests will be

bilateral and practiced using an alpha error rate of 5% without correction for multiplicity.The main moments of interest are baseline (initiation of treatment with tocilizumab), week 12 and 24. Given that this is a non-interventional study, and the evaluation times are not scheduled in advance, appropriate windows around such moments will be defined.The main variable of interest, the proportion of patients treated with tocilizumab at 6 months, will be analyzed descriptively. Confidence intervals (CI) for this and similar variables, such as the IS rate will be calculated using the Clopper-Pearson method.

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)

Other

Data sources (types), other

Prospective patient-based data collection

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