A Prospective Observational Study to Evaluate Long-term Safety of AMGEVITA in Patients With Rheumatoid Arthritis (20160264)

First published: 07/11/2019

Last updated: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/32417

EU PAS number

EUPAS31796

Study ID

32417

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The current study is designed to fulfill a post-authorization commitment to evaluate long-term safety of AMGEVITA and utilizes an existing registry, the BSRBR-RA. This method supports the collection of long-term safety data for new, similar biological product treatments in the postmarketing setting and is an efficient approach for conducting post-authorization safety studies (PASS).

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 08/03/2019

Actual: 08/03/2019

Study start date
Planned: 15/11/2019

Actual: 15/11/2019

Data analysis start date
Planned: 02/06/2027

Date of final study report
Planned: 27/10/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20160264_01.02.06 Public Redacted Protocol Ver 1.0 2019-06-13 English.pdf
(5.06 MB)

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)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective of this study is to estimate the incidence rates of the following safety concerns (identified risks of adalimumab) in patients with RA exposed to AMGEVITA: serious infections (ie, infectious events which require IV antibiotics, hospitalization, or meet other criteria for a serious adverse event)

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective observational cohort study

Study drug and medical condition

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

ADALIMUMAB

Medical condition to be studied

Rheumatoid arthritis

Population studied

Age groups

Adolescents (12 to < 18 years)

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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

300

Study design details

Outcomes

The primary outcome measures are: Incidence of serious infections (ie, infectious events which require IV antibiotics, hospitalization, or meet other criteria for a serious adverse event) in patients with RA exposed to AMGEVITA, The secondary outcome measures are: • Incidence of serious hypersensitivity reactions in patients with RA exposed to AMGEVITA • incidence of other serious adverse events (safety concerns) in patients with RA exposed to AMGEVITA• incidence rates safety concerns from both the BSRBR-RA anti-TNFand nbDMARD comparison cohorts.

Data analysis plan

All analyses will be descriptive. For categorical variables, the frequency and percentage, with 95% CI where appropriate, will be provided. Summary

statistics for continuous variables will include the number of patients, mean, median, SD or standard error, minimum and maximum. Follow-up among the AMGEVITA-treated patients will start from initiation of the drug and end with the occurrence of death, discontinuation of AMGEVITA or the end of the 5-year follow-up period, whichever comes first. For the purposes of context, current incidence rates will also be calculated from both of the following BSRBR-RA comparison cohorts: anti-TNF comparison cohort, which is a cohort of patients receiving an established anti-TNF drug (adalimumab, etanercept or infliximab) who were recruited within 6 months of first exposure. nbDMARD comparison cohort, which is a cohort of patients with similar disease activity receiving conventional systemic DMARDs who have never been exposed to biologic therapy

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Exposure 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