

LONG-TERM SURVEILLANCE STUDY OF RITUXIMAB (MABTHERA)-TREATED PATIENTS WITH GRANULOMATOSIS WITH POLYANGIITIS (GPA) OR MICROSCOPIC POLYANGIITIS (MPA) (RIVAS)

First published: 23/11/2016

Last updated: 14/03/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS16359

Study ID

50725

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study is a non-interventional secondary data safety study in patients with GPA/MPA exposed to rituximab or other available treatments as part of their standard clinical care. Data will be extracted from the Cambridge site within UKIVAS database. Patients in each treatment cohort (rituximab or other available treatment regimens) will be followed from time of disease flare or disease diagnosis since 2003 (year of first use of rituximab) in Cambridge (total target study sample size approximately 400). Patients who switch treatment regimens during the course of their registry follow-up will continue to be followed with date of switching recorded. Data will be extracted to the end of study, loss to follow-up or to withdrawal of consent or death and will be evaluated and patients treated according to physician's standard practice.

Study status

Finalised

Research institutions and networks

Institutions

Addenbrooke's Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Vasculitis Office

Contact details

Study institution contact

Trial Information Support Line TISL

global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

David Jayne

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/12/2015

Study start date

Actual: 07/10/2016

Data analysis start date

Actual: 07/10/2016

Date of final study report

Planned: 30/09/2023

Actual: 20/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

[BE29950_RIVAS_Protocol_Amendment_MARC_Redacted.pdf](#) (1.15 MB)

[RIVAS NIS Protocol Amendment v.2.3 25032020 clean_Redacted.pdf](#) (6.94 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)

Other study registration identification numbers and links

BE29950

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:

RIVAS is a secondary use of data study aimed to provide long-term safety data from the use of rituximab and other available therapies for patients with GPA or MPA.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

RITUXIMAB

Medical condition to be studied

Granulomatosis with polyangiitis

Microscopic polyangiitis

Population studied

Short description of the study population

Patients aged 18 years or older diagnosed with granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) exposed to the rituximab treatment identified through UKIVAS registry.

Inclusion criteria:

1. Clinical diagnosis of GPA/MPA through use of the consensus algorithm for the classification of ANCA vasculitis and polyarteritis nodosa
2. Age \geq 18 years
3. Have given informed consent to participate in the UKIVAS registry
4. Have given informed consent to participate in the RIVAS registry
5. Any patients with GPA/MPA who has received rituximab (MabThera) for vasculitis since 2003
6. Any GPA/MPA patient with disease flare since 2003 who has not received rituximab

Exclusion criteria:

1. Patients with eosinophilic GPA
 2. Unwilling or unable to provide written informed consent for UKIVAS registry
 3. Unwilling or unable to provide written informed consent for RIVAS registry
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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)
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Special population of interest

Other

Special population of interest, other

Patients with granulomatosis with polyangitis and microscopic polyangitis

Estimated number of subjects

400

Study design details

Outcomes

To provide long-term safety data on rituximab-treated patients with GPA/MPA. - To estimate the incidence of serious adverse events (SAEs), including infections, cardiovascular events and malignancies, following rituximab or other available treatments in patients with GPA/MPA. - To compare the incidence of each safety event over time between the rituximab-treated cohort and the cohort treated with other available therapies.

Data analysis plan

The Principal Investigator will retrospectively analyse a pre-specified data-cut within the Cambridge center every 12 months for the cumulative study report. For each patient cohort, variables will be summarized using mean, median, standard deviation and range for continuous data, and counts and percentages for categorical data. Following the methodology used in rheumatoid arthritis, two main analytical approaches will be used depending on the outcome of

interest. For analyses of risk of malignancy, the primary analysis will use an ever-exposed model that includes all person-time since the first drug dose in the study. For all SAEs except malignancy, the primary analysis will be based on a time-on-drug approach that uses a pre-defined risk window after the last administration of rituximab or other available therapies. An outcome of interest occurring during the defined risk window period will be allocated to the preceding treatment identically for both drug regimens.

Documents

Study results

[CSR_Synopsis_BE29950_\(RIVAS\)__Redacted.pdf](#) (125.34 KB)

Study report

[RIVAS_annual_report_2021_December_6_2021.pdf](#) (1.57 MB)

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 source(s), other

Data sources (types)

[Disease 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