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

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Administrative details

PURI

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 institution and networks**

**Institutions**

- **Addenbrooke's Hospital**
  - First published: 01/02/2024
  - Last updated: 01/02/2024

- **Vasculitis Office**

**Contact details**

**Study institution contact**
Trial Information Support Line TISL
  
global.clinical_trial_registry@roche.com

**Primary lead investigator**
David Jayne

**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 data collection

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 ≥ 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

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 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

Data management

Data sources

Data source(s), other
UK and Ireland vasculitis registry (UKIVAS) United Kingdom

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