The RTX-COVAC study: humoral response to COVID-19 vaccination after rituximab, and relation with dose and vaccination timing. A prospective cohort study.

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To investigate, in RA patients, the role of different RTX doses (200, 500 and 1000mg) and timing of RTX on risk of obtaining adequate humeral response against COVID-19 vaccines, by performing a sensitivity analysis on response, using logistic…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON50851

Source
ToetsingOnline

Brief title
RTX-COVAC

Condition

- Autoimmune disorders
- Joint disorders

Synonym
rheumatism, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Sint Maartenskliniek

Intervention

Keyword: covid-19, rheumatoid arthritis, rituximab, vaccination

Outcome measures

Primary outcome

Humoral response (IgT against COVID-19 >= 1.1) 2-4 weeks after second vaccine

dose

Secondary outcome

Humoral response (IgT against COVID-19 >= 1.1) 2-6 months after second vaccine

dose

Humoral response (IgT against COVID-19 >= 1.1) 2-6 weeks after the third

vaccine dose, in the participants with insufficient response after the 2nd

vaccine dose.

Study description

Background summary

Many vaccines are being deployed to prevent corona virus disease 2019 (COVID-19) infections. Although these vaccines appear to be safe and effective in the general population less is known about the effectiveness of these vaccines in patients with rheumatoid arthritis treated with rituximab.
Previous studies showed decreased vaccination response to influenza and pneumococcal vaccinations in RA patients. However, all these studies have been performed with registered high dose RTX (2x 1000 mg), whereas optimal efficacy in RA can be reached with low-dose (1x 1000 mg) or ultra-low dose (1x 500 mg or 1x 200 mg) RTX.
Therefore, we want to investigate the response to the COVID-19 vaccination in patients with RA treated with different doses of RTX (200, 500 and 1000mg), and

the relation to the time between previous RTX administration and vaccination.

Study objective

To investigate, in RA patients, the role of different RTX doses (200, 500 and 1000mg) and timing of RTX on risk of obtaining adequate humeral response against COVID-19 vaccines, by performing a sensitivity analysis on response, using logistic regression.
Study design: Prospective (usual care) cohort study.

Study design

Patients will be requested to provide informed consent prior to the first study visit. Blood will be drawn (6 mL EDTA tube) at 2 or 3 points in time: 2-4 weeks after the last dose of the COVID-19 vaccination and at their next RTX administration. A third blood sample wil be drawn in the participants with insufficient antibody response, to measure response 2-6 weeks after the third vaccine. Serum IgG against COVID-19 will be measured in batch process at the end of the study. Patient, disease and treatment characteristics will be obtained via electronic patient files. Vaccination details will be obtained via patients* vaccination passport or their general practitioner.

Study burden and risks

The burden and risks of the study are very small for the participant, since this study only includes two visits to draw an extra vial of blood (6 mL), of which one is embedded in regular care and the other can be performed at home. A potential benefit for the participant is that they can be informed about their anti-COVID-19 antibody level at the end of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Rheumatoid arthritis: either 2010 EULAR/ACR RA and/or 1987 ACR RA criteria and/or clinical diagnosis of the treating rheumatologist;
* Treatment with at least one dose of rituximab (most of the times 200 mg, 500 mg or 1000 mg one or two times, but all dosages are included) in the year prior to the COVID-19 vaccine;
* Expected to receive a registered COVID-19 vaccine or have received a registered COVID-19 vaccine in the last 6 months;
* *16 years old and mentally competent;
* Ability to read and communicate in Dutch.

Exclusion criteria

* Not eligible (for example allergic to one of vaccine ingredients) or not willing to receive the COVID-19 vaccine;

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2021
Enrollment:	270
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Comirnaty
Product type:	Medicine
Brand name:	COVID-19 vaccine AstraZeneca
Product type:	Medicine
Brand name:	COVID-19 vaccine Moderna

Ethics review

Approved WMO Date:	08-03-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-03-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-11-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-000710-42-NL
CCMO	NL76709.091.21

Study results

Date completed:	16-02-2022
Actual enrolment:	259