Research into the effect of the COVID-19 vaccines on patients with rheumatoid arthritis, treated with rituximab

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28096

Source
Nationaal Trial Register

Brief title
RTX-COVAC

Health condition

Rheumatoid arthritis

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Response against COVID-19 vaccine 2-6 weeks after last vaccine dose, measured by IgT antibody index titre against COVID-19 (IgT >= 1.1)

Amendment:
Response against COVID-19 vaccine 2-6 weeks after third vaccine dose, dichotomized between ‘sufficient’ and ‘insufficient’ response based on the cut-off of the specific assay used.

Secondary outcome

Response against COVID-19 vaccine 3-6 months after last vaccine dose, measured by IgT antibody index titre against COVID-19 (IgT >= 1.1)

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 (RA), treated with rituximab (RTX). Previous studies into influenza and pneumococcal vaccines showed a decreased vaccination response to these vaccinations in RA patients treated with RTX, compared to other antirheumatic drugs. 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) RTX or even ultra-low dose (1x 500 mg or 1x 200 mg) RTX. Therefore, we want to investigate the response to the COVID-19 vaccine in patients with RA treated with different doses of RTX in our clinic (200, 500 and 1000 mg) and the relation to the time between previous RTX administration and vaccination.
We will perform a prospective (usual care) cohort study in which we will determine total immunoglobulin (IgT) titre against COVID-19 at two points in time: the first 2-6 weeks after the last vaccine dose and the second 3-6 months after (combined with the next RTX administration, if possible). In addition to these antibody titre measurements, we will collect vaccination details (type of vaccine, date(s), batch number), information about a prior COVID-19 infection (if applicable) and general information about the RA and the treatment with RTX.

Amendment:
In the autumn of 2021, the Dutch government made a third vaccination available for patients treated with rituximab, because of the decreased humoral response after two vaccines. Therefore, we made an amendment to the existing study, with the aim to investigate humoral response in patients treated with (ultra-)low dose RTX 2-6 weeks after the third vaccine, and the relation between timing and dosing.

Study objective

We hypothesize that the % responders 2-6 weeks after the last vaccine dose in patients with ultra-low dose RTX (1x 500 mg or 1x 200 mg every 6 months) is significantly higher

compared to patients treated with low-dose or registered dose RTX. We also hypothesize that the % responders 2-6 weeks after the last vaccine dose in patients that received the vaccine in the two months prior to the next RTX administration, is significantly higher compared to patients who received the vaccine early (first 4 months) after RTX administration.

Amendment:
We hypothesize that the % responders 2-6 weeks after the third vaccine dose in patients with 200 mg RTX is significantly higher compared to patients treated with 500 or 1000 mg RTX as last dose before first vaccination. We also hypothesize that time since latest RTX is a significantly associated variable with humoral response in univariable logistic regression.

Study design

First blood sample: 2-4 weeks after last vaccine dose;
Second blood sample: 3-6 months after last vaccine dose.
After the second blood sample, the study ends.

Amendment:
Third blood sample: 2-6 weeks after third vaccine dose.
After the third blood sample, the study ends.

Contacts

Public
Sint Maartenskliniek
Celeste van der Togt

024 3272793
Scientific
Sint Maartenskliniek
Celeste van der Togt

024 3272793

Eligibility criteria

Inclusion criteria

Rheumatoid arthritis (either 2010 ACR/EULAR RA criteria and/or 1987 ACR RA criteria and/or clinical diagnosis of the treating rheumatologist);
Treatment with at least one dose of rituximab in the year prior to the first COVID-19 vaccine

dose;
Expected to receive a registered COVID-19 vaccine or has received a registered COVID-19 vaccine in the last 6 months;
> 16 years old and mentally competent;
Ability to read and communicate in Dutch.

Amendment:
Expected to receive a third registered COVID-19 vaccine or has received a third registered COVID-19 vaccine.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2021
Enrollment:	270
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-03-2021
Application type:	First submission

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
NTR-new	NL9342
Other	CMO Arnhem-Nijmegen : 2021-7406

Study results

Summary results

van der Togt CJT, Ten Cate DF, den Broeder N, Rahamat-Langendoen J, van den Bemt BJF, den Broeder AA. Humoral response to Coronavirus Disease-19 vaccines is dependent on dosage and timing of rituximab in patients with rheumatoid arthritis. Rheumatology (Oxford). 2022 Apr 4:keac206. doi: 10.1093/rheumatology/keac206.