

Rituximab in rheumatoid arthritis: is a reduced dose every 6 months equally effective as the regular dose if the patient has low or very low disease activity?

Submission date 05/08/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/03/2018	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Rheumatoid arthritis (RA) is a long-term disease causing pain, swelling and stiffness in the joints. It is a disease of the immune system, known as an autoimmune disease, in which the immune system starts to attack healthy joints. In healthy people, the body produces different types of immune cell. One of these types is the B-cell, which produces antibodies to fight infection. In people with RA, these do not behave properly and produce antibodies which attack a person's own body even if there is no infection. One of the common treatments for RA is the medication rituximab (RTX). In the body, this medication works to reduce the number of B-cells, stopping them from producing antibodies which will attack the healthy cells. This study is looking at people with RA who are in remission. The aim of this study is to find out whether or not lowering the dose of rituximab in these patients will cause the disease to flare up.

Who can participate?

Adults diagnosed with rheumatoid arthritis being treated with rituximab with low disease activity /are in remission

What does the study involve?

Participants are randomly divided into two groups. The first group continues to receive their current doses of rituximab (RTX), of 1000mg every 6 months. The second group receives a lower dose of 500mg every 6 months. Participants in each group continue on these doses for two years. They are then be tested to find out whether or not the activity of the disease has increased.

What are the possible benefits and risks of participating?

There are no immediate benefits of participating in the study. After the results have been analysed (in about 4 years), the time it takes to receive the infusion will be shorter with the reduced dose, causing the treatment to be less inconvenient. Also, the cost of treatment will be less, which could be considered as a benefit. There are no particular risks of participating,

however there is a small risk that patients in the lower dose group may experience return of their disease. In that case, rituximab dose may be raised again or it may be necessary to switch to another medication.

Where is the study run from?
Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
January 2015 to December 2019

Who is funding the study?
Medical University of Vienna (Austria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2015-002156-27

Study information

Scientific Title
Randomized, prospective, active-comparator controlled, patient-blinded study to demonstrate non-inferiority of reduced-dose Rituximab in rheumatoid arthritis patients in low disease activity and remission: the REDOREM study

Acronym
REDOREM

Study objectives

In patients with RA who are in persistent low disease activity or persistent remission a reduced dose of 1x500mg intravenous RTX semi-annually will not lead to a higher frequency of patients experiencing disease flares compared with the continuation of 1x1000mg intravenous RTX semi-annually

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the Medical University of Vienna, 01/09/2015, ref: 1356/2015

Study design

Single-centre randomized prospective active-comparator controlled patient-blinded study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

Bi-annual infusion of rituximab at two doses: 1000 mg or 500 mg

Intervention Type

Drug

Drug/device/biological/vaccine name(s)

Rituximab

Primary outcome(s)

Increased disease activity ("flare") during the treatment period of 2 years. Flare is defined as a change in DAS28 of >1.2 or an increase in DAS28 of 0.6-1.2 if this results in DAS28 >3.2 ("reverse" EULAR improvement criteria). The DAS28 is a composite measure consisting of tender and swollen joint counts, the subjective assessment of disease activity by the patient, and the erythrocyte sedimentation rate (ESR). It will be recorded every three months (at routine visit time points) during the planned observation period of 2 years.

Key secondary outcome(s)

1. Number of patients remaining in low disease activity or remission in the two treatment groups
2. Difference in radiographic progression between the treatment groups over two years
3. Difference in functional outcome between the treatment groups over a monitoring period of two years

Completion date

31/12/2019

Eligibility

Key inclusion criteria

1. Diagnosis of Rheumatoid arthritis (RA) according to the 2010 ACR/EULAR classification criteria (14)
2. Current treatment with RTX (at time of inclusion have already received at least 2 cycles of > / =1000mg RTX at least six months apart) at the Day-Clinic of the Division of Rheumatology of the Medical University of Vienna
3. Persistent low disease activity or clinical remission

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Aged 18 years or younger
2. Receiving rituximab for a disease other than Rheumatoid arthritis
3. Failing to meet criteria for remission or low disease activity at either one of the two successive timepoints (i.e. having a disease activity >10 as measured by the clinical disease activity index, (CDAI))
4. Female patients of childbearing potential not willing to practice effective contraception throughout treatment with RTX and twelve months thereafter
5. Pregnant or lactating women

Date of first enrolment

07/03/2016

Date of final enrolment

31/12/2017

Locations**Countries of recruitment**

Austria

Study participating centre

Medical University of Vienna

Department of Rheumatology

Waehringer Guertel 18-20

Vienna

Austria

A-1090

Sponsor information

Organisation

Medical University of Vienna

ROR

<https://ror.org/05n3x4p02>

Funder(s)

Funder type

University/education

Funder Name

Medizinische Universität Wien

Alternative Name(s)

Medical University of Vienna, MediUni Wien

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Austria

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request