ISRCTN14909030 https://doi.org/10.1186/ISRCTN14909030

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

Registration date
03/09/2015

Overall study status
Completed

Last Edited
12/03/2018

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 does 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

EudraCT/CTIS number
2015-002156-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/01/2015

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

Age group
Adult

Sex
Both

Target number of participants
130

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
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Sponsor information

Organisation
Medical University of Vienna

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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
The results (primary and secondary outcomes) of this trial will be submitted for publication in a peer-reviewed medical journal, regardless of the outcome. It is foreseen that the total duration of the trial (first patient's first visit to last patient's last visit) will be four years, therefore, in case a start is possible in Q4 2015, the trial will be completed in Q1 2020. A submission for publication should be feasible within one year.

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request