Comparison of subcutaneous and intravenous retreatment with ultra-low dose rituximab in rheumatoid arthritis: a randomised open-label non-inferiority trial

Published: 03-09-2020
Last updated: 16-11-2024

The aim of this study is to investigate non-inferiority of rituximab SC 336 mg to rituximab IV 200 mg.

Ethical review	Approved WMO
Status	Completed
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON52719

Source
ToetsingOnline

Brief title
RTX-SC

Condition

- Autoimmune disorders
- Joint disorders

Synonym
arthritis, rheumatic diseases, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: subsidie wordt aangevraagd bij ReumaNederland

Intervention

Keyword: pharmacokinetics, rheumatoid arthritis, rituximab, subcutaneous

Outcome measures

Primary outcome

The main study endpoint is non-inferiority of rituximab 336 mg SC to 200 mg IV,

with the AUC0-6mnd,SC : AUC0-6mnd,IV exceeding 0.8.

Secondary outcome

Secondary outcomes include additional pharmacokinetic parameters, changes in

disease activity, changes in quality of life, suppression of B-cells, presence

of anti-drug antibodies, adverse events and patient preferences.

Study description

Background summary

Recently, the REDO-study has been performed, demonstrating a good response on continued treatment with f ultra-low dose rituximab (1x 500 or 1x 200 mg) in a large proportion of rheumatoid arthritis (RA) patients.1 To further optimize rituximab treatment in terms of patient friendliness and organization of care, subcutaneous administration should be explored.

Study objective

The aim of this study is to investigate non-inferiority of rituximab SC 336 mg to rituximab IV 200 mg.

Study design

Randomised parallel open-label non-inferiority trial

Intervention

Patients will be randomised to rituximab 336 mg subcutaneously or 200 mg intravenous 4-5 months after having received their last dose of rituximab. Randomization will be stratified to the previous rituximab dose (200 or 500 mg) and the use of a concomitant DMARD (combination therapy or monotherapy RTX).

Study burden and risks

The risks in this study include adverse events to rituximab SC and risk of a flare-up of the rheumatoid arthritis. Since patients already receive treatment with (ultra-) low dose rituximab, the chance of additional systemic adverse events and infusion reactions will be absent. Injection site reactions can be expected.
In case the bioavailability is lower than expected, an increase in RA disease activity might occur. Then an extra visit will be planned where disease activity will be measured and extra treatment will be given, if necessary.
Potential benefits of this study include the chance of an injection instead of infusion therapy, which reduces burden of time and co-medication.
Overall, the risks expected in this study are small and manageable.

Contacts

Public
Sint Maartenskliniek

Hengstdal 3
Ubbergen 6574NA
NL
Scientific
Sint Maartenskliniek

Hengstdal 3
Ubbergen 6574NA
NL

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 RA17 and/or 1987 ACR RA18 criteria and/or clinical diagnosis of the treating rheumatologist;
- Patients using rituximab in ultra-low dose: either 200 mg or 500 mg as previous dose, given every 6 months, with or without concomitant methotrexate;
- Having sufficient response to rituximab treatment, operationalized as a DAS28-CRP < 2.9 3-6 months after the last infusion and/or judgment of low disease activity by the treating rheumatologist;
- >=16 years old and mentally competent;
- Ability to read and communicate well in Dutch.

Exclusion criteria

- Previous non-response to ultra-low dose rituximab (DAS28-CRP > 2.9);
- Objection or contraindication to either of the treatment options.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-04-2022
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	MabThera
Generic name:	Rituximab
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Rixathon
Generic name:	Rituximab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-09-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-09-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-12-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-02-2022
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	EUCTR2020-002507-19-NL
CCMO	NL74149.091.20