DE-escalating ocRelizumAb In cLinical and radiological stable MS

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To describe the efficacy and safety of a maintenance versus induction anti-CD20 treatment strategy in pwMS.

Ethical review	Not approved
Status	Will not start
Health condition type	Demyelinating disorders
Study type	Observational non invasive

Summary

ID

NL-OMON51850

Source
ToetsingOnline

Brief title
DERAIL-MS

Condition

- Demyelinating disorders

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anti-CD20, de-escalation, multiple sclerosis

Outcome measures

Primary outcome

The primary endpoint is the proportion of pwMS with new and/or enhancing T2 lesions on brain MRI.

Secondary outcome

The secondary endpoints are the proportion of pwMS with symptomatic infections requiring hospital admission, relapses, confirmed disability progression, NEDA-3, timed 25-foot walk test, nine hole peg test, single digit modality test, serum neurofilament level evolution, SARS-CoV-2 antibodies, lymphocyte repopulation and immunoglobulin level evolution. We will also record the reasons to prioritize induction vs. continuation of maintenance therapy with anti-CD20.

Study description

Background summary

Anti-CD20 monoclonal antibodies (mAb) target B cells and are an established second-line therapy in multiple sclerosis (MS). This drug is currently used as a maintenance therapy, and repeated every 6 months which might result into an unreasonable disadvantage for certain people with MS (pwMS). First, there is emerging evidence that anti-CD20 can be used as an induction therapy (i.e. stopping anti-CD20 infusions after a limited number of infusion cycli) with preserved long-term efficacy. Second, chronic B cell depletion leads to low IgG levels which increases susceptibility to infections. Third, anti-CD20-treated pwMS do not develop an adequate IgG antibody response to vaccines. Fourth, maintenance therapy with anti-CD20 comes at a considerable cost for the Dutch health care system. Based on these evolving insights, the physicians at ErasMS will discuss risks versus benefits of a maintenance and induction strategy in all pwMS on anti-CD20 who received at least 4 treatment cycles.

Study objective

To describe the efficacy and safety of a maintenance versus induction anti-CD20 treatment strategy in pwMS.

Study design

Prospective, observational study. All pwMS who have received at least 4 cycli of anti-CD20 treatment and do not show clinical/radiological evidence of disease activity will be informed about the altered balance between risks versus benefits when continuing their treatment. Subsequently, we will discuss the following three treatment strategies: 1) continuing anti-CD20 infusions, 2) de-escalating anti-CD20 to a first-line treatment or 3) stopping anti-CD20.

Study burden and risks

For all treated pwMS (anti-CD20 or first line treatment), lab tests, physical/technical examinations and site visits will be requested based on clinical grounds. For untreated pwMS who participate in this study, there will be six-monthly blood monitoring and clinic visit whereas outside of the study context a once yearly frequency for these measurements might be more common.

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

1. Age * 18 years
2. Diagnosis of MS according to any version of the McDonald criteria
3. Being treated with anti-CD20 mAb in the context of MS
4. Having received at least 4 cycles with anti-CD20 mAb
5. No signs of clinical or radiological disease activity in the preceding 1 year

Exclusion criteria

1. Inability to comply with yearly MRI and 6-monthly clinical monitoring
2. Inability to make an informed treatment decision because of language barriers

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	66

Type:	Anticipated

Ethics review

Not approved

Date:	04-05-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL80481.078.22