Research into administration of lower dosed rituximab using an injection in patients with Rheumatoid Arthritis

Gepubliceerd: 08-09-2020 Laatst bijgewerkt: 13-12-2022

We expect to find pharmacokinetic non-inferiority between RTX 336 mg subcutaneous and 200 mg IV

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20186

Bron
NTR

Verkorte titel
RTX-SC

Aandoening

Rheumatoid arthritis

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate non-inferiority of rituximab SC 336 mg to rituximab IV 200 mg, with the lower

boundary of the 95% confidence interval of AUC0-6mnd,SC : AUC0-6mnd,IV exceeding the non-inferiority margin of 0.8.

Toelichting onderzoek

Achtergrond van het onderzoek

Rituximab (RTX) is a chimeric antibody directed at CD20 positive B-cells that is authorized for the treatment of rheumatoid arthritis (RA) in the dosage of 2x 1000 mg every six months. A large systematic review showed that low-dose RTX (1x 1000 mg or 2x 500 mg) is as efficacious for RA as this higher dose. Recently, the REDO-study has been performed, demonstrating a good response on continued treatment with even ultra-low dose RTX (1x 500 or 1x 200 mg) for a large proportion of RA patients. After dose optimization, patient friendliness and organization of care might be further improved when rituximab can be administered subcutaneously. Therefore, we want to explore the therapeutic possibilities of subcutaneous (SC) administration of ultra-low dose RTX, by performing a pharmacokinetic non-inferiority study using the already authorized subcutaneous formulation of Roche (MabThera 1400 mg solution for subcutaneous injection (120 mg/ml:11.7 ml), registered for non-Hodgkin lymphoma. Patients with RA, using RTX IV 500 or 200 mg every 6 months, with stable disease activity will be included. Previous non-response to ultra-low dose RTX or a contraindication or objection to receive either therapy are reasons for exclusion. Patients will be randomized between RTX 336 mg subcutaneous or 200 mg intravenous. Blood samples for rituximab serum levels, anti-drug antibodies and CD20+ B-cells will be drawn pre-dose, post-dose (after infusion for the IV group, 2-4 days after injection for the SC group), after 3 months and after 6 months. Disease activity using DAS28-CRP will be measured at baseline, after 3 months and after 6 months. The main endpoint of the study is pharmacokinetic non-inferiority based on AUC0-6months between RTX 200 mg intravenous and 336 mg subcutaneous.

Doel van het onderzoek

We expect to find pharmacokinetic non-inferiority between RTX 336 mg subcutaneous and 200 mg IV

Onderzoeksopzet

Baseline; 3 days (SC only); 3 months; 6 months

Onderzoeksproduct en/of interventie

Rituximab 336 mg subcutaneous (MabThera 1400 mg solution for subcutaneous injection (120 mg/ml:11.7 ml); Rituximab 200 mg intravenous (Rixathon 100 mg concentrate for solution for infusion)

Contactpersonen

Publiek

Sint Maartenskliniek
Celeste van der Togt

024 3272793

Wetenschappelijk

Sint Maartenskliniek
Celeste van der Togt

024 3272793

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Previous non-response to ultra-low dose rituximab (DAS28-CRP > 2.9);
• Objection or contraindication to either of the treatment options;

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	04-10-2020
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-09-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8884
Ander register	CMO Arnhem-Nijmegen : 2020-6779

Resultaten