ANTI-CD20 THERAPY FOR THE TREATMENT OF CHRONIC GRAFT VERSUS HOST DISEASE

Gepubliceerd: 17-03-2008 Laatst bijgewerkt: 18-08-2022

Anti CD20 therapy will result in complete or partial response in patients with chronic GVHD, who do not respond to first line treatment.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27822

Bron
NTR

Verkorte titel
N/A

Aandoening

chronic graft-versus-host disease, allogeneic stem cell transplantation,
B-cell depletion

Ondersteuning

Primaire sponsor: University Medical Centre Utrecht
P.O. Box 85500
3508 GA Utrecht, The Netherlands
Overige ondersteuning: Dutch Cancer Society, KWF2006-3685

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Proportion of patients with a complete or partial response

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Currently, there is no established therapy for steroid-refractory chronic GVHD. Manipulation of T cells has not been effective, while there is evidence that manipulation of the B cell compartment leads to clinical improvement.

Objective: To study prospectively the clinical efficacy of Rituximab treatment of steroid refractory chronic GVHD

Study design: Non-randomized phase II single center study

Study population: Patients with a steroid refractory chronic GVHD with skin localization
Intervention: Rituximab at a weekly dose of 375 mg/m2 i.v. for four weeks.

Main study parameters/endpoints The primary endpoint of the study will be the proportion of complete and partial responses. The secondary endpoint consists of immune-histochemical improvement in skin biopsies.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness. The burden and risks associated with this trial is very low. Potential benefit is that in vivo depletion of B cells with the CD20-specific antibody rituximab may result in amelioration of chronic GVHD symptoms. Side effects of rituximab are mostly associated with the first infusion and usually mild. Blood samples (50 ml each) will be collected at 8 different time points. Skin biopsies will be obtained at 3 different time points.

Doel van het onderzoek

Anti CD20 therapy will result in complete or partial response in patients with chronic GVHD, who do not respond to first line treatment.

Onderzoeksopzet

T=0 pre-treatment

Monthly until T=13 (1 year follow up)

Onderzoeksproduct en/of interventie

Treatment with rituximab (anti-CD20 monoclonal antibody) 375 mg/m2 i.v. for four weeks (weekly)

Monthly clinical report and physical examination

3 x skin biopsy

3 x Shirmer test

7 x 40ml blood drawn

Contactpersonen

Publiek

P.O. Box 85500

J. Kuball
University Medical Centre Utrecht
Department of Hematology/B02.226
Utrecht 3508 GA
The Netherlands
+31 88 7557230

Wetenschappelijk

P.O. Box 85500

J. Kuball
University Medical Centre Utrecht
Department of Hematology/B02.226
Utrecht 3508 GA
The Netherlands
+31 88 7557230

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > = 18 years

2. Chronic GVHD, including skin localization, refractory or dependent to first line treatment consisting of steroids and/or ciclosporine. Refractory cGVHD is defined as progressive cGVHD after at least 2 weeks of first line treatment or no response after 4 weeks of first line treatment.. Dependent cGVHD is defined as an inability to taper immunosuppressive treatment.

3. Written informed consent

4. WHO performance status ¡Ü 2

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Relapse and a life expectancy of < 6 months

2. Life expectancy of < 6 months

3. Systemic infections: active viral infections, including HIV

4. Other treatment for GVHD apart from steroids, ciclosporine and, when applicable, standard GVHD prevention

5. Inadequate renal and liver function, i.e. creatinin or bilirubin >2.5 x the upper normal value

6. Neutrophil count <1.5 x 109/l and hemoglobin level <6.2 mmol/l

7. Pregnant or lactating

8. Any experimental therapy within 30 days prior to randomization

9. Known sensitivity or allergy to murine products

10. Any other co-existing medical or psychological condition that will preclude participation in the study or compromise ability to give informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2006
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	17-03-2008
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	NL1177
NTR-old	NTR1222
Ander register	KWF : 2006-3685
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A