Prospective study on the effects of rituximab on synovial tissue of patients with rheumatoid arthritis.

Gepubliceerd: 25-12-2006 Laatst bijgewerkt: 13-12-2022

Rituximab treatment leads to a decrease in synovial B cells. The clinical response is related to the decrease in synovial B cell numbers.

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

Samenvatting

ID

NL-OMON19978

Bron
NTR

Verkorte titel
Rituximab II AMC study

Aandoening

rheumatoid arthritis

Ondersteuning

Primaire sponsor: Academic Medical Center/University of Amsterdam
Overige ondersteuning: Dutch Arthritis Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate the synovial tissue response to rituximab treatment and to identify possible

predictors of clinical response in patients with rheumatoid arthritis (RA).
RA patients undergo synovial biopsy before, 4 and 16 weeks after
initiation of rituximab treatment without peri-infusional corticosteroids. Immunohistochemical analysis is performed and stained sections are analyzed by digital image analysis. Statistical analysis is performed to find predictors of clinical response after 24 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

This open label study will include patients with active rheumatoid arthritis. Before and 4 and 16 weeks after treatment with rituximab (2 infusions with 1000 mg rituximab without premedication with corticosteroids), synovial biopsies will be taken with a mini-arthroscopy from a clinically inflamed joint. The same joint will be used for each arthroscopy. Immunohistochemical analysis of synovial tissue will be performed using digital image analysis. Clinical features like disease activity using the DAS28 will be measured regularly. At different time points the number of B cells will be measured in peripheral blood by FACS analysis

Doel van het onderzoek

Rituximab treatment leads to a decrease in synovial B cells. The clinical response is related to the decrease in synovial B cell numbers.

Onderzoeksproduct en/of interventie

The patients underwent an arthroscopic synovial biopsy procedure directly before and 4 and 16 weeks after receiving two infusions of rituximab without methylprednisolone premedication. Immunohistochemical analysis was performed on the synovial tissue.

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Medicine, Division of
Clinical Immunology and Rheumatology
P.O. Box 22660

Koen Vos
Address Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662171

Wetenschappelijk

Academic Medical Center (AMC), Department of Medicine, Division of Clinical Immunology and Rheumatology
P.O. Box 22660

Koen Vos
Address Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662171

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients (18 years or older) with rheumatoid arthritis (ACR 1987 criteria) with active disease (at least 4/28 swollen and at least 4/28 painfull joints, and either ESR 28 mm or CRP 15 mg/l or morning stiffness 45 min);
2. Rheumatoid factor and/or anti-CCP positive;
3. Stable doses methotrexate (5-30 mg);
4. Stable doses prednisone (0-10 mg);
5. Previous anti-TNF treatment is allowed.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous treatment with rituximab;
2. Intra-articular or parenteral corticosteroids within 4 weeks prior to inclusion.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2005
Aantal proefpersonen:	32
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	25-12-2006
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	NL837
NTR-old	NTR851

Register	ID
Ander register	: N/A
ISRCTN	ISRCTN05568900

Resultaten

Samenvatting resultaten
N/A