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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19978

Source
Nationaal Trial Register

Brief title
Rituximab II AMC study

Health condition

rheumatoid arthritis

Sponsors and support

Primary sponsor: Academic Medical Center/University of Amsterdam
Source(s) of monetary or material Support: Dutch Arthritis Foundation

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. To study the safety and effectivity of a fixed rituximab retreatment protocol;
2. To study influence of rituximab on anti-drug antibody formation;
3. To explore pharmacokinetic and pharmacodynamc effects in blood and synovial tissue

Study description

Background summary

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

Study objective

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2005
Enrollment:	32
Type:	Actual

Ethics review

Positive opinion

Date:	25-12-2006
Application type:	First submission

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
NTR-new	NL837
NTR-old	NTR851

Register	ID
Other	: N/A
ISRCTN	ISRCTN05568900

Study results

Summary results
N/A