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

Submission date	Recruitment status	[ ] Prospectively registered
27/06/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/06/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/10/2008	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR851

Study information

Scientific Title

Acronym
Rituximab II AMC study

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the Medical Ethics Committee of the Academic Medical Center, University of Amsterdam on the 25th March 2005 (ref: 05/038).

Study design
Prospective open-labelled study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
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.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Rituximab

Primary outcome measure
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 analysed by digital image analysis. Statistical analysis is performed to find predictors of clinical response after 24 weeks.

Timepoints: one, four and six months after therapy.

Secondary outcome measures
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 pharmacodynamic effects in blood and synovial tissue

Timepoints: one, four and six months after therapy.

Overall study start date
01/03/2005

Completion date
01/03/2008

Eligibility

Key inclusion criteria
1. Patients (18 years or older) with rheumatoid arthritis (American College of Rheumatology [ACR] 1987 criteria) with active disease (at least 4/28 swollen and at least 4/28 painful joints, and either Erythrocyte Sedimentation Rate [ESR] 28 mm or C-Reactive Protein [CRP] 15 mg/l or morning stiffness for 45 minutes)
2. Rheumatoid factor and/or anti-Cyclic Citrullinated Peptide antibody (anti-CCP) positive
3. Stable doses of methotrexate (5 - 30 mg)
4. Stable doses of prednisone (0 - 10 mg)
5. Previous anti-Tumour Necrosis Factor (anti-TNF) treatment is allowed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
32

Key exclusion criteria
1. Previous treatment with rituximab
2. Intra-articular or parenteral corticosteroids within four weeks prior to inclusion

Date of first enrolment
01/03/2005

Date of final enrolment
01/03/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Division of Clinical Immunology and Rheumatology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
Dutch Arthritis Association (Reumafonds) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2008		Yes	No