

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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).

Primary study design

Interventional

Study design

Prospective open-labelled study

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

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)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Research organisation

Funder Name

Dutch Arthritis Association (Reumafonds) (The Netherlands)

Results and Publications

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