Prevention of RA by B cell directed therapy.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28176

Source
NTR

Brief title
PRAIRI

Health condition

pre-clinical RA

Sponsors and support

Primary sponsor: Academic Medical Center/University of Amsterdam, Amsterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

To study if B cell depleting therapy delays/prevents the development of arthritis in patients with preclinical RA.
The primary outcome measure is defined by the time to occurence of clinical arthritis.

Secondary outcome

1. To determine if prevention of RA by B cell depleting therapy is cost-effective and safe;

2. To study the effect of B cell depleting therapy in patients with pre-clinical RA;

3. To explore the pharmacodynamics of B cell therapy in this patient.

Study description

Background summary

This randomized, double blind, placebo-controlled prevention study is investigator driven and initiated by the Division of Clinical Immunology and Rheumatology at the Academic Medical Center (AMC), University of Amsterdam. The study will be performed in cooperation with the Maastricht University Medical Center (MUMC), Maastricht and the University Medical Center Groningen (UMCG), Groningen, and Rijnstate Hospital, Arnhem. Ninety people will be randomized to B cell depleting therapy and placebo.
The patients will be followed for four years. If arthritis becomes manifest, patients will receive appropiate therapy chosen by their rheumatologist.

Study objective

It is hypothesized that treatment with B cell directed therapy in the pre-clinical phase of RA will decrease the development of arthritis.

Study design

Patients will be followed for four years, with a study visite every four weeks up to week 16, every eight weeks up to week 36, and yearly until study completion. During each visit extensive standardized clinical assessments will be performed, consistent with standard clinical trial design in RA.

Intervention

All patients will receive B cell depleting therapy or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with pre-clinical RA, defined by the presence of arthralgia and at least one of the following features:

1. IgM-rheumatoid factor (IgM-RF) of > 12.5 IU/ml;

2. Anti-citrullinated peptide antibodies (ACPA) in the serum of > 25 IU/ml;

3. At least one of the following features:

A. CRP > 3 mg/l;

B. ESR > 28 mm/h;

C. Subclinical synovitis as assessed by ultrasound;

D. Subclinical synovitis as assessed by MRI.

Exclusion criteria

1. Clinically evident arthritis;

2. History of arthritis;

3. Use of DMARDs;

4. Previous treatment with any cell depleting therapies;

5. Known active infection;

6. immunodeficiency;

7. Pregnant women.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-01-2010
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-08-2009
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	NL1857
NTR-old	NTR1969
Other	ABR nummer 27282 : MEC 09/048 # 09.17.1241
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A