Primary prevention of rheumatoid arthritis.

No registrations found.

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

Summary

ID

NL-OMON26301

Source
Nationaal Trial Register

Brief title
N/A

Health condition

rheumatoid arthritis

Sponsors and support

Primary sponsor: Prof.dr. B.A.C. Dijkmans
VUMC/Jan van Breemen Instituut
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

50% reduction of the concentration of the increased antibodies after 6 months compared to no treatment.

Secondary outcome

Frequency of rheumatoid arthritis after 5 years compared to no treatment.

Study description

Background summary

Rheumatoid arthritis (RA) has a preclinical phase. Before the disease manifests itself autoantibodies such as rheumatoid factor (RF) and antibodies against citrullinated proteins (anti-CCP) can be found. In one half of blood donors who developed RA later we found an elevated concentration in serum of RF and/or anti-CCP at an average of five years before the start of the symptoms, whereas control donors hardly had positive results.
The predictive value for the development of RA within five years of a positive test for RF and/or anti-CCP varies from 2% (no risk factors) to 44% (multi-case families). This risk increases further if the genetic risk factor HLA-DR4 is also present. The target group for this study consists of persons with or without joint complaints (possibly with family members with RA), but without
arthritis, and also with both increased values of RF and/or anti-CCP and a positive test for HLA-DR4. These persons have an increased risk of developing RA and therefore can be considered candidates for a preventive intervention.
Such a preventive intervention should be short and safe. Therefore the choice was made for 1-2 injections with a prednisone-like substance, with proven efficacy in patients who already have RA. The goal of this preventive intervention is to achieve a decrease into the normal range or at least a 50% decrease of the concentration of these antibodies after 6 months. It is expected that a decrease of the antibody concentration is a good predictor for the cancellation or the postponement of
the development of manifest RA.
In this doubleblind randomised study one hundred persons will be included. These will mainly be family members of RA patients and patients with joint complaints who have been referred by their family physician. After the intervention the participants will be followed for at least five years.

Study objective

1-2 intramuscular injections with 100 mg dexamethason in persons without arthritis but with elevated serum levels of rheumatoid factor and or anti-CCP will lead to a reduction in antibody concentrations after 6 months and possibly to a lower frequency of rheumatoiud arthritis after 5 years, in comparison to no treatment.

Intervention

1-2 intramuscular injections with 100 mg dexamethason with 6 weeks interval (2nd injection with verum depends on response to first injection) or twice placebo.

Contacts

Public
Jan van Breemen Institute,
Dr. Jan van Breemenstraat 2
D. Schaardenburg, van
Dr. Jan van Breemenstraat 2
Amsterdam 1056 AB
The Netherlands
+31 (0)20 5896589
Scientific
Jan van Breemen Institute,
Dr. Jan van Breemenstraat 2
D. Schaardenburg, van
Dr. Jan van Breemenstraat 2
Amsterdam 1056 AB
The Netherlands
+31 (0)20 5896589

Eligibility criteria

Inclusion criteria

1. Age 18-70 years for RF+, 18+ for aCCP+;

2. Twice increased IgM-RF and/or anti-CCP with 4+ weeks interval;

3. HLA-DR SE positive.

Exclusion criteria

Situations with possible false positive RF:

1. Auto-immune diseases;

2. Active infection with hepatitis C or Ebstein Barr virus;

3. Recent chemotherapy;

4. Comorbidity with decreased life expectancy;

5. Corticosteroid use for another disease;

6. Contra-indications for corticosteroids: diabetes mellitus, osteoporosis;

7. Pregnancy or lactation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2005
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-08-2005
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	NL102
NTR-old	NTR133
Other	: N/A
ISRCTN	ISRCTN73232918

Study results

Summary results

Arthritis Rheum 2004; 50: 380-6

Arthritis Rheum 2004; 50: 2423-7