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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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

Bron

NTR

Verkorte titel

N/A

Aandoening

rheumatoid arthritis

Ondersteuning

Primaire sponsor :	Prof.dr. B.A.C. Dijkmans VUMC/Jan van Breemen Instituut
Overige ondersteuning :	ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type :	Interventie onderzoek
Onderzoeksmodel :	Parallel
Blindering :	Dubbelblind
Controle :	Placebo

Deelname

Nederland

Status :	Werving gestart
(Verwachte) startdatum :	01-10-2005
Aantal proefpersonen :	80
Type :	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum :	23-08-2005
Soort :	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL102
NTR-old	NTR133
Ander register	: N/A
ISRCTN	ISRCTN73232918

Resultaten

Samenvatting resultaten

Arthritis Rheum 2004; 50: 380-6

Arthritis Rheum 2004; 50: 2423-7