Prevention of RA by B cell directed therapy.

Gepubliceerd: 28-08-2009 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON28176

Bron
NTR

Verkorte titel
PRAIRI

Aandoening

pre-clinical RA

Ondersteuning

Primaire sponsor: Academic Medical Center/University of Amsterdam, Amsterdam
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

All patients will receive B cell depleting therapy or placebo.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-01-2010
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

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

Resultaten

Samenvatting resultaten
N/A