Effects of abatacept (Orencia®) on biomarkers in synovial tissue in patients with rheumatoid arthritis.

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There might be biomarkers in infected synovial tissue which have predicting value on the effectiveness of Abatacept on RA.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22398

Bron
NTR

Aandoening

RA
Reumatoide Artritis
Rheumatoid Arthritis
Reuma

Ondersteuning

Primaire sponsor: AMC Amsterdam
Overige ondersteuning: nvt

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To study changes in synovial inflammation in serial biopsy samples following administration

of abatacept therapy to subjects with active rheumatoid arthritis.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

There might be biomarkers in infected synovial tissue which have predicting value on the effectiveness of Abatacept on RA.

Onderzoeksopzet

In total there will be 9 study visits:

Screening, baseline, week 2, week 4, week 8, week 12, week 16, week 20 and week 24. There will be a ± 3 day deviation for all return visits. All visits will be fixed with reference to the baseline visit.

Onderzoeksproduct en/of interventie

To study changes in synovial inflammation in serial biopsy samples following the administration of abatacept in patients with active rheumatoid arthritis.

Synovial biopsies from an actively inflamed joint (knee, ankle or wrist) will be obtained by mini-arthroscopy or ultrasound guided biopsy before administration of abatacept and at week 16 of treatment.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Men/women suffering from rheumatoid arthritis, based on the American Rheumatism Association (ARA) 1987 criteria, who failed methotrexate treatment, will be eligible for the study;

2. Patients in ARA functional classes I, II, and III may be included.

In addition, patients must fulfill the following criteria at baseline:

1. DAS 28-CRP > 3.2;

2. Be > 18 years of age and < 85 years;

3. Use concurrent methotrexate treatment (5 - 30 mg/week; stable for at least 28 days before study initiation) during the study. Subjects may be taking nonsteroidal anti-inflammatory drugs, provided the dose and frequency have been stable for at least 28 days. Subjects may be receiving prednisone therapy < 10 mg/day provided that the dosage has been stable for at least 1 month prior to entry.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. Breastfeeding;

3. Subjects who are impaired, incapacitated, or incapable of completing study related

assessments;

4. Subjects who meet diagnostic criteria for any other rheumatic disease (e.g., lupus erythematous);

5. Subjects who have previously received treatment with an investigational biologic RA therapy, anti-TNF therapy, rituximab, tocilizumab or abatacept;

6. Subjects with active vasculitis of a major organ system with the exception of rheumatoid nodules;

7. Subjects with current symptoms of severe, progressive, or uncontrolled renal, hepatic, hematological, gastrointestinal, pulmonary, cardiac, neurological, or cerebral disease, or other medical conditions that, in the opinion of the investigator, might place the subject at unacceptable risk for participation in this study;

8. Subjects with a history of cancer within the last five years (other than nonmelanoma skin cell cancers cured by local resection). Existing non-melanoma skin cell cancers must be removed prior to dosing;

9. Subjects who have clinically significant drug or alcohol abuse;

10. Subjects with any serious bacterial infection within the last 3 months, unless treated and resolved with antibiotics, or any chronic bacterial infection (such as chronic pyelonephritis, osteomyelitis and bronchiectasis);

11. Subjects at risk for tuberculosis (TB). Specifically, subjects with:

A. A history of active TB within the last 3 years even if it was treated;

B. A history of active TB greater than 3 years ago unless there is documentation that the prior anti-TB treatment was appropriate in duration and type;

C. Current clinical, radiographic or laboratory evidence of active TB;

D. Latent TB which was not successfully treated.

12. Subjects with herpes zoster or cytomegalovirus (CMV) that resolved less than 2 months prior to signing informed consent;

13. Subjects with evidence (as assessed by the Investigator) of active or latent bacterial or viral infections at the time of potential enrollment, including subjects with evidence of Human Immunodeficiency Virus (HIV), Hepatitis B or Hepatitis C infection detected during screening;

14. Subject who have received any live vaccines within 3 months of the anticipated first dose of study medication or who will have need of a live vaccine at any time following Day 1 of the

study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2010
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-11-2010
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	NL2512
NTR-old	NTR2630
Ander register	METC AMC : 10/173
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A