Tocilizumab met biopten cohort. Tocilizumab with biopsy cohort.

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Changes in synovial inflammation in serial biopsy samples following the administration of tocilizumab in patients with active RA.

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

Samenvatting

ID

NL-OMON25859

Bron
NTR

Verkorte titel
Tocilizumab met biopten cohort

Aandoening

RA, reuma, rheumatiod arthritis

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: nvt

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to study changes in synovial inflammation in serial biopsy samples following the administration of tocilizumab in patients with active RA.

Toelichting onderzoek

Achtergrond van het onderzoek

A monocenter, open-label, prospective study with a 4-week screening period, a 16-week treatment period and 4 weeks follow-up period for safety reasons.

Doel van het onderzoek

Changes in synovial inflammation in serial biopsy
samples following the administration of tocilizumab in patients with active RA.

Onderzoeksopzet

Clinical evaluation of joint pain and swelling will be performed at baseline and repeated after 2, 4, 6, 8, 12, and 16 weeks of treatment. Patients will be seen for efficacy and safety assessments in accordance with standard guidelines for clinical
practice.

In total there will be nine study visits: Screening, week 0 (i.e., baseline), week 2, week 4, week 6, week 8, week 12, week 16, and week 20 (i.e., follow-up). For week 4 and on, there will be a 3-day deviation for all return visits.

Onderzoeksproduct en/of interventie

Observational with invasive measuring.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Males/females suffering from RA, classified according to the 2010 ACR/EULAR classification criteria for RA, who have active disease (DAS28 „d3.2) despite adequate methorexate treatment, will be eligible for the study. Patients in ARA functional classes I, II, and III may be included.
In addition, patients must fulfill the following criteria at baseline:

1. Be >18 years and < 70 years of age;

2. Use concurrent MTX treatment (5-30 mg/week; stable for at least 28 days before study initiation) during the study. Subjects may be taking NSAIDs or oral corticosteroids (prednisone equivalent < 10 mg/day), provided that the dosage has been stable for at least 28 days prior to entry;

3. Have an inflamed knee, ankle or wrist joint.

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 erythematosus);

5. Subjects who have received treatment with rituximab less than 1 year before baseline or abatacept less than 1 month before baseline;

6. Subjects who have received treatment with tocilizumab;

7. Current use of oral corticosteroids (if exceeding a prednisone equivalent of 10 mg daily) or DMARDs other than MTX; intra-articular injections of corticosteroids 28 days or less before inclusion;

8. Current use of TNF blocking agents, such as etanercept, adalimumab, infliximab, golimumab or certolizumab. Washout periods are depending on pharmacokinetic profile of the various agents;

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

10. Subjects with current symptoms of severe, progressive, or uncontrolled renal, hepatic, hematologic, gastrointestinal, pulmonary, cardiac, neurologic, 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;

11. Subjects with a history of cancer within the last five years (other than nonmelanoma skin cell cancers cured by local resection);

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

13. 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);

14. 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 > 3 years ago unless there is documentation that 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.

15. Subjects with herpes zoster or cytomegalovirus infection that resolved <2 months prior to signing informed consent;

16. 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, hepatitis B or hepatitis C
infection detected during screening;

17. Subjects 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:	01-05-2011
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-05-2011
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	NL2771
NTR-old	NTR2911
Ander register	METC AMC : 2011-084
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A