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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22398

Source
Nationaal Trial Register

Health condition

RA
Reumatoide Artritis
Rheumatoid Arthritis
Reuma

Sponsors and support

Primary sponsor: AMC Amsterdam
Source(s) of monetary or material Support: nvt

Intervention

Outcome measures

Primary outcome

To study changes in synovial inflammation in serial biopsy samples following administration of abatacept therapy to subjects with active rheumatoid arthritis.

Secondary outcome

1. Assess clinical response;

2. Assess cellular responses of synovial explants to inflammatory stimuli, and/or antagonists, before and after treatment with abatacept;

3. Identify synovial biomarkers predictive of the clinical response to abatacept treatment;

4. Investigate the changes in phenotypes of peripheral blood mononuclear cells (PBMCs).

Study description

Background summary

N/A

Study objective

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

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2010
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A