Adalimumab bij perifere spondyloartritis zonder AS of PsA.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23446

Source
NTR

Brief title
N/A

Health condition

spondyloartritis, spondylitis ankylosans, artritis psoriatica

Sponsors and support

Primary sponsor: dr Baeten
Source(s) of monetary or material Support: investigator initiated
3e geldstroom en mede gefinancieerd door industrie

Intervention

Outcome measures

Primary outcome

The primary objective is to evaluate the efficacy and safety of adalimumab for the treatment of peripheral spondyloarthritis not fulfilling the classification criteria for AS or PsA.

Secondary outcome

The secondary objectives of this study are to assess the effect of adalimumab on:

1. Function and quality of life;

2. Serum biomarkers;

3. Synovial biomarkers.

Study description

Background summary

N/A

Study objective

Effectiviteit en veiligheid van behandeling met adalimumab worden geevalueerd bij patienten met perifere spondyloartritis.

Study design

Following a screening period of 3 weeks, patients with active peripheral spondyloarthritis not fulfilling the classification criteria for AS or PsA (see appendix 1) will be enrolled into a (1:1) 12-week randomized double-blind, placebo-controlled treatment period, followed by a 12 week open extension where all patients will receive adalimumab (Humira□). Patients are allowed to use concomitant non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids (prednisone equivalent ≤ 10 mg/day) and disease-modifying anti-rheumatic drugs (DMARDs) provided the dose has been stable for at least 4 weeks prior to baseline.

In total there will be 6 study visits: Screening, baseline, week 6, 12, 18, and 24.
There will be a ± 3-day deviation for all return visits. All visits will be fixed with reference to the baseline visit.

Intervention

Geneesmiddel: humira/adalimumab EU/1/03/256/007-010.

De eerste 12 weken worden de patienten behandeld met adalimumab (40 mg per 2 weken, subcutane injectie) of placebo (ratio 1:1). De laatste 12 weken worden alle patienten behandeld met adalimumab.

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Eligibility criteria

Inclusion criteria

1. Leeftijd 18-70;

2. 3 maanden diagnose perifere spondyloartritis en niet voldoen aan classificatie spondylitis ankylosans;

3. Matig tot ernstig actief;

4. Minstens 1 gezwollen en 1 pijnlijk gewricht;

5. Onvoldoende respons op NSAID;

6. Vrouwelijke patienten moeten geen kinderen (meer) kunnen krijgen of betrouwbare methode van geboortecontrole tot 150 dagen na studie.

Exclusion criteria

1. In 2 maanden voor start behandeling met anti-TNF of andere studie-medicatie;

2. In 4 weken voor start een intra articulaire inject met corticosteroiden;

3. Actieve gewrichtsziekte die kan interfereren met het beoordelen van artritis;

4. Voorgeschiedenis van actieve tuberculosis;

5. Recente of persisterende infectie waarvoor hospitalizatie of antibiotische behandeling vereist is in de 4 weken voor start van studie;

6. Significante (voor)geschiedenis van hartziekte, nierziekte, neurologische ziekten, metabole ziekten of elke andere ziekte die de deelname aan de studie kan verstoren;

7. (Voor)geschiedenis van malignieit in de voorbije 10 jaar (uitz basaal celcarcinoma vd huid).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2009
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	07-05-2009
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	NL696
NTR-old	NTR1806
Other	METC AMC : 08/322
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A