A prospective study for the effects of treatment with adalimumab in patients with psoriasis and psoriatic arthritis.

No registrations found.

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

Summary

ID

NL-OMON25856

Source
NTR

Brief title
ADAPs

Health condition

Psoriatic arthritis and psoriasis

Sponsors and support

Primary sponsor: Investigator initiated study
Work is carried out by AWR van Kuijk (Rheumatology), M de Groot and MA de Rie (Dermatology)
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Changes in cellular infiltrate and cytokine expression, measured by immunohistochemical

analysis, in biopsies of skin and synovium at week 4 compared baseline.

Secondary outcome

1. Clinical and functional scores at week 4 and week 12 compared to baseline: Psoriasis Area and Severity Index (PASI), Tender Joint Count (TJC), Swollen Joint Count (SJC), Visual Analogue Scale (VAS) for disease activity by patient and physician, levels of ESR and CRP in blood, Health Assessment Questionnaire (HAQ).

Study description

Background summary

A monocenter, prospective, double blinded phase 4 trial in patients with psoriasis and psoriatic arthritis to study the effects of adalimumab on biological markers in skin and synovium. The trial has 2 phases: in the first 4 weeks patients are randomized and treated with adalimumab 40 mg or placebo (1:1), biopsies of skin and synovium (by arthroscopy of a large joint) are collected at baseline and week 4; after week 4 all patients are treated with adalimumab open label and followed up to week 12.

Study objective

Find the best predictive biomarker for respons to treatment.

Study design

N/A

Intervention

Adalimumab 40 mg or placebo once every other week subcutaneous (first 4 weeks), open label adalimumab 40 mg after week 4.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with psoriatic arthritis and psoriasis;

2. Age 18-80 years;

3. At least 2 painful and 2 swollen joints;

4. Inadequate respons to NSAIDs;

5. Effective contraception;

6. Signed informed consent.

Exclusion criteria

1. Use of another DMARD than methotrexate within 4 weeks of baseline;

2. Intra-articular injection with corticosteroids within 4 weeks of baseline;

3. Other TNF-blocking treatment or treatment with another biological agent within 2 months of baseline;

4. Another skin or connective tissue disease that interferes with the assessment of psoriasis or psoriatic arthritis;

5. Active or latent tuberculosis;

6. Infection with HIV, hepatitis B or hepatitis C virus;

7. Severe comorbidity;

8. Malignancy other than basal cell carcinoma of skin within 10 years of baseline;

9. Pregnancy or breastfeeding.

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):	01-02-2006
Enrollment:	24
Type:	Actual

Ethics review

Positive opinion

Date:	19-12-2006
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	NL833
NTR-old	NTR846
Other	: N/A
ISRCTN	ISRCTN23328456

Study results

Summary results
N/A