

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

<b>Submission date</b> 16/01/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/04/2016	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

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

### Acronym

ADAPs

### Study objectives

Find the best predictive biomarker for response to treatment.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Medical Ethical Committee of the Academic Medical Centre/University of Amsterdam, 10/08 /2005, ref: MEC 05/162

### Study design

Randomised placebo-controlled parallel-group double-blinded trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Psoriatic arthritis, psoriasis

### Interventions

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

### Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Adalimumab

**Primary outcome measure**

Changes in cellular infiltrate and cytokine expression, measured by immunohistochemical analysis, in biopsies of skin and synovium at week four compared to baseline.

**Secondary outcome measures**

Clinical and functional scores at week four 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 Erythrocyte Sedimentation Rate (ESR) and C-Reactive Protein (CRP) in blood, Health Assessment Questionnaire (HAQ).

**Overall study start date**

01/02/2006

**Completion date**

01/05/2007

## Eligibility

**Key inclusion criteria**

1. Patients with psoriatic arthritis and psoriasis
2. Age 18 to 80 years
3. At least two painful and two swollen joints
4. Inadequate response to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
5. Effective contraception
6. Signed informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

24

**Key exclusion criteria**

1. Use of another Disease Modifying Anti-Rheumatic Drug (DMARD) than methotrexate within four weeks of baseline

2. Intra-articular injection with corticosteroids within four weeks of baseline
3. Other Tumour Necrotising Factor (TNF)-blocking treatment or treatment with another biological agent within two 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 Human Immunodeficiency Virus (HIV), hepatitis B or hepatitis C virus
7. Severe comorbidity
8. Malignancy other than basal cell carcinoma of skin within ten years of baseline
9. Pregnancy or breastfeeding

**Date of first enrolment**

01/02/2006

**Date of final enrolment**

01/05/2007

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre****Academic Medical Center (AMC)**

Amsterdam

Netherlands

1100 DD

## Sponsor information

**Organisation**

Academic Medical Center (AMC) (Netherlands)

**Sponsor details**

Division of Clinical Immunology and Rheumatology

P.O. Box 22660

Amsterdam

Netherlands

1100 DD

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.amc.uva.nl/#http://www.amc.uva.nl/>

ROR

<https://ror.org/03t4gr691>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Academisch Medisch Centrum (AMC) (Netherlands)

### Alternative Name(s)

Academic Medical Center, AMC

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Universities (academic only)

### Location

Netherlands

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	03/09/2010		Yes	No
<a href="#">Results article</a>	results	01/01/2016		Yes	No