

# 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

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## Additional identifiers

## 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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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).

**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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## 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)

**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, Centre Médical Académique, ACADEMISCH MEDISCH CENTRUM AMSTERDAM, Academic Medical Center (Amsterdam), AMC

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
Universities (academic only)

**Location**  
Netherlands

## Results and Publications

**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