

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

Submission date 16/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/01/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/04/2016	Condition category 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

Protocol serial number
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

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, AMC

Funding Body Type

Private sector 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?
Results article	results	03/09/2010		Yes	No
Results article	results	01/01/2016		Yes	No