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

Submission date	Recruitment status	[_] Prospectively registered
16/01/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/04/2016	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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 respons 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 Drugs (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?
Results article	results	03/09/2010		Yes	No
Results article	results	01/01/2016		Yes	No