Computer Assisted Management of Early Rheumatoid Arthritis-II: Does prednisone inhibit progression of joint damage if early RA is treated very intensively with DMARDs?

No registrations found.

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

Summary

ID

NL-OMON24306

Source
Nationaal Trial Register

Brief title
CAMERA-II

Health condition

Rheumatoid Arthritis

Sponsors and support

Primary sponsor: University Medical Center Utrecht (The Netherlands) and Abbott
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Radiologic joint damage of hands and feet according to the van der Heijde modification of the Sharp scoring method.

Secondary outcome

Number of patients in remission, in which remission is defined as:

1. Number of swollen joints = 0;

2. Plus at least two out of three following criteria:

2.a Number of swollen joints <3;

2.b ESR< 20 mm/hr1st;

2.c VAS general well being < 20 mm.

Study description

Background summary

If early RA is treated very intensively with DMARDs according to modern clinical standards, does prednisone 10 mg daily inhibit progression of joint damage according to the van der Heijde modification of the Sharp scoring method?

Study objective

Prednisone inhibits progression of joint damage in early RA-patients, even when intensive treatment, according to a strict computer-assisted protocol, is applied.

Study design

N/A

Intervention

10 mg of prednisolone daily vs placebo in addition to DMARDs. Two year study.

Contacts

Public

University Medical Center Utrecht (UMCU), Department of Rheumatology and Clinical Immunology, F02.127,
P.O. Box 85500
A.C.A. Marijnissen
Utrecht 3508 GA
The Netherlands
+31 (0)30 2509758
Scientific
University Medical Center Utrecht (UMCU), Department of Rheumatology and Clinical Immunology, F02.127,
P.O. Box 85500
A.C.A. Marijnissen
Utrecht 3508 GA
The Netherlands
+31 (0)30 2509758

Eligibility criteria

Inclusion criteria

1. Rheumatoid Arthritis, defined according to the revised American College of Rheumatology (ACR) criteria for Rheumatoid Arthritis;

2. A disease duration of less than 1 year, estimated by the rheumatologist;

3. Age > 18 years;

4. No previous treatment with DMARDs or oral glucocorticoids;

5. Written informed consent by the patient.

Exclusion criteria

1. Abnormal renal function (Cockroft < 75 ml/min);

2. Abnormal liver function (ASAT/ALAT > 2* normal), active or recent hepatitis, cirrhosis;

3. Major co morbidities like malignancies, severe diabetic mellitus, severe infections, severe cardio and/or respiratory diseases;

4. Leukopenia and/or thrombocytopenia;

5. Inadequate birth control conception, pregnancy, and / or breastfeeding;

6. Treatment with cytoxic or immunosuppressive drugs within a period of 3 months prior to the study;

7. Alcohol intake >2 units per day or drug abuse, presently or in the past;

8. Psychiatric or mental disorders which makes adherence to the study protocol impossible;

9. Taking part into another clinical trial;

10. Osteoporotic vertebral fractures.

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):	01-04-2003
Enrollment:	220
Type:	Actual

Ethics review

Positive opinion

Date:	23-03-2006
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	NL570
NTR-old	NTR626
Other	: N/A
ISRCTN	ISRCTN70365169

Study results

Summary results
Research based on:
Everdingen AA van, Jacobs JWG, Reesema DR van, Bijlsma JWJ. Low-dose prednisone therapy for patients with early active rheumatoid arthritis: clinical efficacy, disease-modifying properties, and side effects. A randomized, double-blind placebo-controlled clinical trial. Ann Intern Med 2002: 136: 1-12.