

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

Submission date 28/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/03/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/09/2020	Condition category Musculoskeletal Diseases	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

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

Acronym

CAMERA-II

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Rheumatoid arthritis (RA)

Interventions

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

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Prednisone and DMARDs

Primary outcome measure

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

Secondary outcome measures

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. Erythrocyte sedimentation rate (ESR) <20 mm/1st hour
 - 2.c. Visual analogue scale (VAS) of general well being <20 mm

Overall study start date

01/04/2003

Completion date

01/04/2007

Eligibility**Key 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

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Key exclusion criteria

1. Abnormal renal function (Cockroft <75 ml/min)
2. Abnormal liver function (aspartate aminotransferase [ASAT]/alanine aminotransferase [ALAT] >2 x 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 contraception, pregnancy, and/or breastfeeding
6. Treatment with cytotoxic 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 in another clinical trial
10. Osteoporotic vertebral fractures

Date of first enrolment

01/04/2003

Date of final enrolment

01/04/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Medical Center Utrecht (UMCU)

Utrecht

Netherlands

3508 GA

Sponsor information**Organisation**

University Medical Center Utrecht

Sponsor details

P.O. Box 85500

Utrecht

Netherlands

3508 GA

Sponsor type

University/education

Website

<http://www.umcutrecht.nl/nl/>

ROR

<https://ror.org/0575yy874>

Funder(s)

Funder type

Industry

Funder Name

University Medical Center Utrecht

Funder Name

Abbott Laboratories

Alternative Name(s)

Abbott, Abbott U.S., Abbott Alkaloidal Company

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

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	06/03/2012		Yes	No
Results article	results	01/01/2013		Yes	No
Results article	results	09/09/2020	11/09/2020	Yes	No