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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

Registration date
29/03/2006

Last Edited
11/09/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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 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 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

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, The Abbott Alkaloidal Company

Funding Body Type
Government organisation

Funding Body Subtype

For-profit companies (industry)

Location
United States of America

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