ISRCTN32484878 https://doi.org/10.1186/ISRCTN32484878

Combination anti-rheumatic drugs in early rheumatoid arthritis

Submission date	Recruitment status
25/10/2000	No longer recruiting
Registration date	**Overall study status**
25/10/2000	Completed
Last Edited	**Condition category**
22/09/2016	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G9722622

Study information

Scientific Title
Combination Anti-Rheumatic Drugs in Early Rheumatoid Arthritis

Acronym
CARDERA

Study objectives
To investigate if the combination of cyclosporin and/or oral steroids with methotrexate in early rheumatoid arthritis (RA) reduces the proportion of patients who develop new erosions within two years.

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)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Orthopaedics, rheumatology

Interventions
Patients will be randomised to receive:
1. Methotrexate alone
2. Methotrexate plus prednisolone
3. Methotrexate plus cyclosporin
4. Methotrexate plus prednisolone plus cyclosporin

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methotrexate, prednisolone, cyclosporin

Primary outcome measure
The proportion of patients with one or more new erosions on X-rays of hands and feet

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

Completion date
23/02/2005

Eligibility

Key inclusion criteria
1. RA by the 1987 criteria of the American College of Rheumatology
2. Disease duration of less than 24 months
3. The clinical need for treatment with a slow-acting anti-rheumatic drug (SAARD) as shown by evidence of active RA
4. Patients must be willing and able to give informed consent
5. Age greater than 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
468

Key exclusion criteria
1. Other forms of inflammatory arthritis (e.g. psoriatic arthritis, systemic lupus erythematosus)
2. Current oral steroids for RA or other conditions (e.g. asthma)
3. Contra-indications to methotrexate
4. Other serious medical disorders (e.g. hepatic failure, cardiac failure, current malignant disease)
5. Females of child bearing potential who are not taking adequate contraceptive protection

6. Contra-indications to cyclosporin therapy
7. Neutrophil count less than 1.5 x 10^12 per decilitre or platelet count less than 100 x 10^12 per decilitre
8. Abnormal liver function test (gamma glutamyl transferase [gGT] greater than 3 x or aspartate aminotransferase [AST]/alanine aminotransferase [ALT] greater than 2 x upper limit of normal)

Date of first enrolment
01/01/2000

Date of final enrolment
23/02/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College Hospital (Dulwich)
London
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/05/2008		Yes	No
Results article	results	16/01/2014		Yes	No
Other publications	secondary analysis	26/08/2016		Yes	No