Combination anti-rheumatic drugs in early rheumatoid arthritis

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

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 United Kingdom SE5 9RJ

Sponsor information

Organisation Medical Research Council (MRC) (UK)

Sponsor details 20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

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

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Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs	
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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