

Can monthly low dose intramuscular (IM) steroids prevent erosive damage in established rheumatoid arthritis? A randomised placebo controlled trial

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| Submission date 10/07/2002 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 10/07/2002 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 02/10/2007 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

C0560

Study information

Scientific Title

Study objectives

To evaluate the benefits of 120 mg intramuscular (IM) depomedrone versus placebo in patients with established Rheumatoid Arthritis (RA) whose disease was inadequately controlled by existing Disease Modifying Anti-Rheumatic Drugs (DMARDs).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research ethics committees at each collaborating centre approved the trial. All patients enrolled gave informed consent.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

Patients will be randomised to receive either:

1. Monthly IM injections of 120 mg depomedrone
2. Sterile normal saline as placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Depomedrone

Primary outcome measure

1. Disease activity assessed every 6 months using:
 - 1.1. Numbers of swollen and tender joints (out of 28)
 - 1.2. Articular pain (100 mm Visual Analogue Scale [VAS])
 - 1.3. Patients and physicians global assessments (100 mm VAS)
 - 1.4. ESR
 - 1.5. C-Reactive Protein (CRP)
 - 1.6. Health Assessment Questionnaire (HAQ) scores
 - 1.7. 28 joint count Disease Activity Scores (DAS28)
2. Radiological damage in the hands and feet assessed every 12 months using a modification of Larsens method
3. Adverse effects assessed every 6 months, including specific information on fractures, hypertension, hyperglycaemia, weight gain, and infections. Bone density was assessed in the lumbar spine and hip by Dual energy X ray Absorptiometry (DXA) at 0 and 24 months

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/11/1997

Completion date

01/04/2003

Eligibility**Key inclusion criteria**

1. Age equal to or more than 18 years
2. Diagnosis of rheumatoid arthritis according to the 1987 American College of Rheumatology criteria
3. Disease duration equal to or more than 2 years
4. One or more erosions on plain X-rays of the hands, wrists and feet
5. Continuous treatment with a Slow-Acting Anti-Rheumatic Drug (SAARD) for at least 3 months (parenteral gold, penicillamine, sulphasalazine, methotrexate, azathioprine and cyclosporin)
6. Continuing active disease with over 6 swollen joints and an Erythrocyte Sedimentation Rate (ESR) over 30 mm/h

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

91

Key exclusion criteria

1. End stage joint destruction (Larsen score greater than 100)
2. Previous or current oral steroid treatment
3. Contraindications to parenteral steroids (for example, recent gastric ulcer perforation or bleed)
4. Serious comorbidity (for example, end stage renal or liver disease)
5. Patients not taking DMARDs, taking experimental drugs, taking DMARDs that have no effect on x-ray progression (for example, antimalarial drugs), or taking DMARDs which may interact poorly with IM depot steroids

Date of first enrolment

01/11/1997

Date of final enrolment

01/04/2003

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Academic Department of Rheumatology

London

United Kingdom

SE22 8PT

Sponsor information**Organisation**

Arthritis Research Campaign (ARC) (UK)

Sponsor details

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St Mary's Court

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info@arc.org.uk

Sponsor type
Charity

Website
<http://www.arc.org.uk>

ROR
<https://ror.org/02jkpm469>

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (UK)

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 | 01/09/2005 | | Yes | No |