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

Submission date
10/07/2002

Recruitment status
No longer recruiting

Registration date
10/07/2002

Overall study status
Completed

Last Edited
02/10/2007

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Academic Department of Rheumatology
London
United Kingdom
SE22 8PT

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (UK)

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	01/09/2005		Yes	No