

Intramuscular depomedrone in very early inflammatory polyarthritis

Submission date 05/02/2002	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 05/02/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/08/2011	Condition category Musculoskeletal Diseases	☐ 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
S0671

Study information

Scientific Title

Acronym

STIVEA

Study objectives

That treating patients with very early inflammatory polyarthritis (less than 10 weeks duration) with a three week course of IM steroid will prevent a substantial proportion of cases from evolving into rheumatoid arthritis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised placebo controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Inflammatory polyarthritis

Interventions

Patients will be randomised to receive:

1. Either weekly injections of 80 mg depomedrone (methylprednisolone) deep into the gluteal muscles for 3 weeks
2. Placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Depomedrone (active ingredient: methylprednisolone)

Primary outcome(s)

The need to start second-line drug therapy (e.g. methotrexate, sulphasalazine) by the 6 month assessment.

Key secondary outcome(s)

1. Whether the patient has satisfied classification criteria for rheumatoid arthritis
2. The presence of radiological erosions in the hands or feet at 12 months
3. The change in physical disability and clinical diagnosis

Completion date

01/06/2006

Eligibility

Key inclusion criteria

Patients aged 18 years or more with inflammatory polyarthritis with a duration of 4 - 10 weeks.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/06/2003

Date of final enrolment

01/06/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

ARC Epidemiology Unit

Manchester

United Kingdom

M13 9PT

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	01/03/2010		Yes	No