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Intramuscular depomedrone in very early inflammatory polyarthritis

Submission date	Recruitment status	[X] Prospectively registered
05/02/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/02/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/08/2011	Musculoskeletal Diseases	

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
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

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

Secondary outcome measures
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

Overall study start date
01/06/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
346

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
England

United Kingdom

Study participating centre
ARC Epidemiology Unit
Manchester
United Kingdom
M13 9PT

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details
Copeman House
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Sponsor type
Charity

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

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name

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	01/03/2010		Yes	No