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A prospective randomised placebo controlled trial of treatment for fibrosing alveolitis in scleroderma

Submission date 15/07/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/07/2002	**Overall study status** Completed	
Last Edited 03/10/2007	**Condition category** 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
D0554

Study information

Scientific Title

Acronym
FAST study

Study objectives
Does routine treatment with cyclophosphamide, azathioprine and prednisolone improve outcomes in fibrosing alveolitis associated with scleroderma?

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Fibrosing alveolitis in scleroderma

Interventions
Intravenous cyclophosphamide plus prednisolone for 6 months followed by azathioprine for 2.5 years or placebo for all drugs

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Cyclophosphamide, azathioprine and prednisolone

Primary outcome measure
1. Change in percent predicted Forced Vital Capacity (FVC)
2. Change in single-breath diffusing capacity for carbon monoxide (DLCO)

Secondary outcome measures
1. Changes in appearance on high-resolution computed tomography
2. Change in dyspnoea scores

Overall study start date
01/10/1998

Completion date
31/10/2003

Eligibility

Key inclusion criteria
1. Aged 18 - 75 years
2. American College of Rheumatology (ACR) criteria for scleroderma
3. Evidence for fibrosing alveolitis - High Resolution Computed Tomography (HRCT) or surgical biopsy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/1998

Date of final enrolment
31/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton Hospital
London
United Kingdom
SW3 6MP

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details
Copeman House
St Mary's Court
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Derbyshire
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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

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	01/12/2006		Yes	No