

The use of a randomised controlled trial of autologous stem cell transplantation (ASCT) versus mobilisation alone to investigate the pathogenic role of T-cells in patients with severe rheumatoid arthritis

Submission date 12/09/2003	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/07/2011	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr P Emery

Contact details

Rheumatology and Rehabilitation Research Unit
36 Clarendon Road
Leeds
United Kingdom
LS2 9LN
+44 0113 392 3995
p.emery@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0436118138

Study information

Scientific Title

Study objectives

1. To assess the ability of a mobilising dose of cyclophosphamide to reduce disease activity and increase response to previously ineffective therapy in comparison to full ASCT.
2. To assess the ability of maintenance therapy post ASCT to prevent relapse.

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Rheumatoid arthritis (RA)

Interventions

Laboratory study; Randomised controlled trial, Random allocation to:

- A. Autologous stem cell transplantation
- B. Mobilisation alone

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

RA quality of life questionnaire, health assessment questionnaire. Tender and swollen joint counts. Inflammatory markers. Histological analysis.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/2001

Completion date

01/07/2006

Reason abandoned (if study stopped)

Insufficient recruitment

Eligibility

Key inclusion criteria

Patients with rheumatoid arthritis who have failed conventional therapy. Patients will be enrolled from specialist RA clinics.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/12/2001

Date of final enrolment

01/07/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Rheumatology and Rehabilitation Research Unit
Leeds
United Kingdom
LS2 9LN

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Charity

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Funder Name
Arthritis Research Campaign

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