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	Recruitment status	Prospectively registered
12/09/2003	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Stopped	☐ Results
Last Edited	Condition category	Individual participant data
04/07/2011	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/07/2006

Reason abandoned (if study stopped)

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre Rheumatology and Rehabilitation Research Unit

Leeds United Kingdom LS2 9LN

Sponsor information

Funder(s)

Funder type

Charity

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

Funder Name

Arthritis Research Campaign

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration