ISRCTN52892553 https://doi.org/10.1186/ISRCTN52892553

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

Registration date
12/09/2003

Overall study status
Stopped

Last Edited
04/07/2011

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
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