A Randomised Study of High-Dose Chemotherapy/ Radiotherapy and Autologous Bone Marrow Transplantation in Patients with High Grade Non-Hodgkin's Lymphoma in First Complete Remission

Submission date	Recruitment status	Prospectively registered
19/08/2002	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2002	Completed	Results
Last Edited	Condition category	Individual participant data
08/11/2012	Cancer	Record updated in last year

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SNLG NHLV(A)

Study information

Scientific Title

Study objectives

Not provided at time of registration

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

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Lymphoma (non-Hodgkin's)

Interventions

All patients receive induction chemotherapy with CHOP or VAPEC-B. Patients in complete or good partial remission following induction receive radiotherapy to the areas of bulky disease.

Patients are then randomised as follows:

GOOD RISK PATIENTS: Good risk patients are randomised to one of two treatment arms:

- 1. Arm A: No treatment
- 2. Arm B: High dose melphan and autologous bone marrow transplant (ABMT)

INTERMEDIATE/POOR PATIENTS: Patients are randomised to one of two treatment arms:

- 3. Arm C: High dose melphan and ABMT
- 4. Arm D: Patients receive high dose melphan, total body irradiation 10.5 Gy in three fractions over 24 h plus ABMT or a BEAM chemotherapy transplant

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1995

Completion date

31/12/2004

Eligibility

Key inclusion criteria

- 1. Patients with high grade non-Hodgkin's lymphoma
- 2. Stage I-IV disease, stage I and II patients must require chemotherapy
- 3. Aged 15 to 65 years
- 4. Adequate marrow, hepatic and renal function
- 5. Patients with localised gut lymphoma, Burkitt's lymphoma and lymphoblastic T-cell with large mediastinal mass are excluded
- 6. No central nervous system (CNS) involvement
- 7. No previous malignant disease except skin or cervical carcinoma stage I

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

01/01/1995

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre UKCCCR Register Co-ordinator

London United Kingdom NW1 2DA

Sponsor information

Organisation

Scotland & Newcastle Lymphoma Group (UK)

Sponsor details

Medical Statistics Unit, Department of Public Health Sciences University of Edinburgh Medical School Teviot Place Edinburgh United Kingdom EH8 9AG

Sponsor type

Research organisation

Funder(s)

Funder type

Research organisation

Funder Name

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration