

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 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/11/2012	Condition category Cancer	<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

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Additional identifiers

Protocol serial number
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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1995

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Scotland & Newcastle Lymphoma Group (UK)

Funder(s)

Funder type

Research organisation

Funder Name

Scotland & Newcastle Lymphoma Group (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration