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# 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

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| **Submission date**<br>19/08/2002 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>08/11/2012 | **Condition category**<br>Cancer | [ ] Individual participant data<br>[ ] 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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## 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