# 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 protocol

Not provided at time of registration

## **Contact information**

## Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

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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

#### **Study outputs**

Output type **Details** Date created Date added Peer reviewed? Patient-facing? Participant information sheet Participant information sheet 11/11/2025 No

Yes