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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

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

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
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
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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name

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