ISRCTN97344827 https://doi.org/10.1186/ISRCTN97344827

A randomised trial to evaluate early high dose therapy and autologous bone marrow transplantation as part of planned initial therapy for poor risk intermediate/high grade non-Hodgkin's lymphoma

Submission date	Recruitment status	[_] Prospectively registered
01/07/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/01/2019	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00003578

Protocol serial number
LY02

Study information

Scientific Title
A randomised trial to evaluate early high dose therapy and autologous bone marrow transplantation as part of planned initial therapy for poor risk intermediate/high grade non-Hodgkin's lymphoma

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)
Treatment

Health condition(s) or problem(s) studied
Lymphoma (non-Hodgkin's)

Interventions
Following randomisation patients receive standard chemotherapy with cyclophosphamide, hydroxydaunorubicin, vincristine and prednisone (CHOP) to be repeated every 21 days for three courses. Patients who show partial or complete response following initial chemotherapy are treated according to the initial randomisation:

1. Regimen A: Continue standard chemotherapy with (CHOP) to be given for two courses beyond complete remission with a minimum of six courses or until progression.

2. Regimen B: High dose therapy with BCNU, etoposide, cytosine-arabinoside and melphan plus ABMT.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cyclophosphamide, hydroxydaunorubicin, vincristine, prednisone, etoposide, cytosine-arabinoside, melphan

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/10/2001

Eligibility

Key inclusion criteria
1. Age 16-65 years
2. No medical conditions other than lymphoma, prohibiting intensive therapy. No systemic treatment for cancer in the previous 5 years
3. Histology: Follicular large cell lymphoma; Diffuse mixed cell lymphoma; Diffuse large cell lymphoma; Diffuse immunoblastic lymphoma
4. Full clinical staging to include Computed Tomography (CT) scanning of abdomen and bone marrow trephine biopsy
5. Poor prognostic features, defined as the presence of two or three of: Stage III or IV; Lactic dehydrogenase (LDH) > normal; Performance status 2-4 (Eastern Cooperative Oncology Group [ECOG]-World Health Organisation [WHO])

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1996

Date of final enrolment
31/10/2001

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2010	25/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes