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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00003578

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1996

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

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1996

Date of final enrolment
31/10/2001

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
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WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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

Study outputs

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