

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 01/07/2001	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/01/2019	Condition category Cancer	☐ Individual participant data

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

Primary study design

Interventional

Study design

Randomised controlled trial

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-arabioside and melphan plus ABMT.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cyclophosphamide, hydroxydaunorubicin, vincristine, prednisone, etoposide, cytosine-arabioside, 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