

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

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|--|---|--|
| Submission date 01/07/2001 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 01/07/2001 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 25/01/2019 | Condition category Cancer | <input type="checkbox"/> 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

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-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 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

United Kingdom

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 |