







A randomised phase III study of intensive therapy with or without autologous bone marrow transplant (ABMT) in relapsed intermediate and high-grade non-hodgkin's lymphomas

Submission date 19/08/2002	Recruitment status No longer recruiting	 Retrospectively registered
		 Protocol not yet added
Registration date 19/08/2002	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 21/01/2019	Condition category Cancer	 Raw data not yet added
		 Study completed

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

PARMA

Study information

Scientific Title

A randomised phase III study of intensive therapy with or without autologous bone marrow transplant (ABMT) in relapsed intermediate and high-grade non-hodgkin's lymphomas

Study hypothesis

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)

Not Specified

Participant information sheet

Condition

Lymphoma (non-Hodgkin's)

Interventions

Following registration all patients receive two courses of chemotherapy with dexamethasone, cisplatin and cytarabine (DHAP).

Patients who meet all the eligibility criteria and who have shown a response to initial treatment are randomised to either:

1. Regimen A: Involved field radiotherapy, 26 Gy in twenty fractions of 1.3 Gy. Radiotherapy to be given twice daily. Following radiotherapy patients receive chemotherapy carmustine,

etoposide, cytarabine and cyclophosphamide (BEAC) and ABMT.

2. Regimen B: Four further courses of DHAP chemotherapy followed by involved field radiotherapy, 35 Gy in twenty fractions, to all sites of initial bulky disease.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Dexamethasone, cisplatin, cytarabine

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1990

Overall study end date

30/06/1994

Eligibility

Participant inclusion criteria

1. Aged 16 to 60 years
2. Relapsed intermediate and high grade lymphoma
3. Patients must have previously been treated with an adriamycin-containing regimen or COM or COMLA
4. No central nervous system (CNS) or bone marrow involvement at relapse
5. Patients must have previously reached a first complete remission on induction regimen
6. Only first and second relapse patients are eligible

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

Not provided at time of registration

Participant exclusion criteria

Not provided at time of registration

Recruitment start date

01/01/1990

Recruitment end date

30/06/1994

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

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 (CRUK) (UK)

Alternative Name(s)

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	07/12/1995		Yes	No