

# 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

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>19/08/2002   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>19/08/2002 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>21/01/2019       | <b>Condition category</b><br>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

**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 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)****Health condition(s) or problem(s) studied**

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(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

30/06/1994

## Eligibility

**Key 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex****Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/1990

**Date of final enrolment**

30/06/1994

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

UKCCCR Register Co-ordinator

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 (CRUK) (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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 07/12/1995   |            | Yes            | No              |