# 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	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>	
19/08/2002		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
19/08/2002	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
21/01/2019	Cancer		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

# Secondary identifying numbers

**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

## 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

#### 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 measure

Not provided at time of registration

#### Secondary outcome measures

Not provided at time of registration

## Overall study start date

01/01/1990

#### 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

# Age group

Adult

#### Sex

**Not Specified** 

# Target number of participants

Not provided at time of registration

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/01/1990

# Date of final enrolment

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)

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	07/12/1995		Yes	No