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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 21/01/2019	**Condition category** Cancer	

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

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
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WC2A 3PX
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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