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The European CUP trial: a randomised trial in adults with poor risk relapsed follicular non-hodgkin's lymphoma

Submission date	Recruitment status	[_] Prospectively registered
19/08/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/07/2014	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
ECUP

Study information

Scientific Title

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)
Not Specified

Health condition(s) or problem(s) studied
Lymphoma (non-Hodgkin's)

Interventions
Following registration all patients receive three, 3 week, cycles of chemotherapy with cyclophosphamide, adriamycin, vincristine and prednisone (CHOP).

Patients who achieve a complete or partial response are randomised to one of three treatment groups:
1. Group A: Chemotherapy, three further cycles of CHOP.
2. Group B High dose therapy with cyclophosphamide and total body irradiation, 8 Gy or 12 Gy midplane dose in a single fraction at a dose rate of 0.15-0.3 Gy/min, followed by unpurged ABMT.
3. Group C: High dose therapy with cyclophosphamide and total body irradiation, 8 Gy or 12 Gy midplane dose in a single fraction at a dose rate of 0.15-0.3 Gy/min, followed by purged ABMT.

Randomisation to Group A is optional. Prior to randomisation clinicians must choose to randomise between all treatment or Group 2 and Group 3 only.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
30/04/1997

Eligibility

Key inclusion criteria
1. Relapsed follicular non-Hodgkin's lymphoma, after a first or subsequent remission, requiring therapy because of at least one of the following:
1.1. B symptoms
1.2. Rapidly progressive disease
1.3. Bone marrow failure
1.4. Life threatening organ failure
2. Aged 15 - 65 years
3. No central nervous system (CNS) involvement
4. No previous radiotherapy greater than 2000 cGy to the mediastinum or abdomen, precluding total body irradiation
5. No previous myeloablative therapy
6. No prior malignancies, except non-melanomatous skin cancer or cervical carcinoma stage I
7. Adequate cardiac, neurologic, liver and renal function
8. No evidence of histlogically proven transformation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/04/1992

Date of final enrolment
30/04/1997

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Baxter AG (Switzerland)

ROR
https://ror.org/052wab383

Funder(s)

Funder type
Industry

Funder Name
Baxter Healthcare (UK)

Results and Publications

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	01/03/2000		Yes	No