

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

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/07/2014	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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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 histologically 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