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# CHOP versus PMItCEBO with/without G-CSF in patients aged sixty years plus with non-hodgkin's lymphoma

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| **Submission date**<br>19/08/2002 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | |
| **Last Edited**<br>22/10/2018 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
http://cancerhelp.cancerresearchuk.org/trials/a-trial-of-chemotherapy-for-people-over-60-with-aggressive-non-hodgkins-lymphoma

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
767

# Study information

## Scientific Title
A phase III trial comparing a cyclophosphamide, adriamycin, vincristine and prednisolone (CHOP) regimen to a mitoxantrone, cyclophosphamide, etoposide, bleomycin, vincristine and prednisolone (PMItCEBO) regimen with or without granulocyte colony-stimulating factor (G-CSF) in patients aged sixty years plus with non-hodgkin's lymphoma

## Acronym
BNLI 60+

## Study objectives
1. To compare the efficacy of mitoxantrone, cyclophosphamide, etoposide, bleomycin, vincristine and prednisolone (PMitCEBO) and cyclophosphamide, adriamycin, vincristine and prednisolone (CHOP) using the study endpoints of overall survival, failure free-survival, disease specific survival, disease free survival, complete response (CR) rate, toxic death rate and toxicity
2. To compare the efficacy of the addition of granulocyte colony-stimulating factor (G-CSF) using the endpoints of failure free survival, overall survival, disease specific survival, disease free survival, neutropenia, dose intensity in patient hospitalisation days, toxic death rates and antibiotic use

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved by the Human Research Ethics Committees of all participating centres (ref: 98/2/52)

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Non-Hodgkin's lymphoma

## Interventions
1. CHOP/G-CSF Regimen: chemotherapy with cyclophosphamide, adriamycin, vincristine and prednisolone (CHOP), cycle repeated every 21 days for six to eight cycles plus G-CSF.

2. CHOP Regimen: chemotherapy with CHOP repeated every 21 days for six to eight cycles.
3. PMitCEBO/G-CSF Regimen: Chemotherapy with Mitoxantrone, cyclophosphamide, etoposide, bleomycin, vincristine and prednisolone (PMitCEBO), cycle repeated every 14 days for four to eight cycles plus G-CSF.
4. PMitCEBO Regimen: Chemotherapy MitCEBO, cycle repeated every 14 days for four to eight cycles.

### Intervention Type
Drug

### Phase
Phase III

### Drug/device/biological/vaccine name(s)
Cyclophosphamide, adriamycin, vincristine and prednisolone (CHOP), mitoxantrone, cyclophosphamide, etoposide, bleomycin, vincristine and prednisolone (PMItCEBO), granulocyte colony-stimulating factor (G-CSF)

### Primary outcome measure
Failure free survival

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/12/1996

### Completion date
20/04/2004

## Eligibility

### Key inclusion criteria
1. Aged at least 60 years
2. Newly presenting aggressive non-Hodgkin's lymphoma
3. Bulky stage IA and stages IB - IV
4. Patients must be free from any other irreversible medical condition that would drastically limit their life span or prohibit the use of combination chemotherapy
5. Adequate renal, hepatic and cardiac function
6. No previous malignancy
7. No central nervous system (CNS) involvement with non-Hodgkin's lymphoma

### Participant type(s)
Patient

### Age group
Senior

### Sex
Both

### Target number of participants
Planned sample size: 880

### Key exclusion criteria
Patients with lymphoblastic and Burkitt's lymphoma

### Date of first enrolment
01/12/1996

### Date of final enrolment
20/04/2004

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**90 Tottenham Court Road**
London
United Kingdom
W1T 4TJ

## Sponsor information

### Organisation
Lymphoma Research Trust (UK)

### Sponsor details
Trustees Department
5th Floor East
250 Euston Road
London
United Kingdom
NW1 2PG

### Sponsor type
Charity

### Website
http://www.lymphoma-research-trust.org.uk/

### ROR

https://ror.org/01e2zk874

# Funder(s)

**Funder type**
Charity

**Funder Name**
Lymphoma Research Trust (UK)

# 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? |
|---|---|---|---|---|---|
| Plain English results | | | | No | Yes |
| Results article | results | 18/05/2009 | | Yes | No |