

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

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

Failure free survival

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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

United Kingdom

England

## Study participating centre

90 Tottenham Court Road

London

United Kingdom

W1T 4TJ

## Sponsor information

### Organisation

Lymphoma Research Trust (UK)

### ROR

<https://ror.org/01e2zk874>

## Funder(s)

### Funder type

Charity

### Funder Name

Lymphoma Research Trust (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?
<a href="#">Results article</a>	results	18/05/2009		Yes	No
<a href="#">Plain English results</a>				No	Yes

