# Phase III Trial comparing CHOP to PmitCEBO in Good Risk patients with Histologically Aggressive Non-Hodgkin's Lymphoma

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
19/08/2002		Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/08/2002	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
27/09/2019	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

#### Contact name

Dr--

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

NCT00005867

Secondary identifying numbers

# Study information

#### Scientific Title

Phase III Trial comparing CHOP to PmitCEBO in Good Risk patients with Histologically Aggressive Non-Hodgkin's Lymphoma

#### Acronym

Not Applicable

## **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)

Treatment

#### Participant information sheet

## Health condition(s) or problem(s) studied

Lymphoma (non-Hodgkin's)

#### **Interventions**

- 1. CHOP regimen: Chemotherapy with cyclophosphamide, doxorubicin, vincristine and prednisolone repeated every 21 days for 6-8 cycles
- 2. PmitCEBO regimen: Chemotherapy with mitoxantrone, cyclophosphamide, etoposide, bleomycin, vincristine and prednisolone. Repeated every 14 days for 4-8 cycles

#### Intervention Type

Drug

#### **Phase**

## Drug/device/biological/vaccine name(s)

**Various** 

## Primary outcome measure

Not provided at time of registration

## Secondary outcome measures

Not provided at time of registration

## Overall study start date

10/12/1998

#### Completion date

31/12/2004

## **Eligibility**

## Key inclusion criteria

- 1. Previously untreated non-Hodgkin's Lymphoma of the following types: follicular large cell lymphoma, diffuse mixed cell lymphoma diffuse large cell lymphoma diffuse immunoblastic lymphoma 0r Revised European/American Lymphoma (REAL) classification: diffuse large B peripheral T cell lymphoma
- 2. Bulky stage IA and stages IB-IV (Ann Arbour staging system)
- 3. Age 18-59 years
- 4. Measurable or evaluable disease
- 5. Good prognosis, defined as the presence of no more than one of the following adverse features: Stage III/IV Lactic dehydrogenase (LDH) >upper limit of normal Performance status 2-4 (Eastern Cooperative Oncology Group [ECOG]-World Health Organisation [WHO]) Adequate bone marrow function, indicated by Haemoglobin  $\geq$ 10 g/dL Neutrophils  $\geq$ 2 x 10^9/L Platelets  $\geq$ 100 x 10^9/L
- 6. Written informed consent

## Participant type(s)

Patient

#### Age group

Senior

## Lower age limit

18 Years

## Upper age limit

59 Years

#### Sex

Both

## Target number of participants

## Not provided at time of registration

## Key exclusion criteria

Does not meet inclusion criteria

## Date of first enrolment

10/12/1998

#### Date of final enrolment

31/12/2004

## Locations

## Countries of recruitment

England

**United Kingdom** 

# Study participating centre UKCCCR Register Co-ordinator

London United Kingdom NW1 2DA

# Sponsor information

#### Organisation

British National Lymphoma Investigation (BNLI) (UK)

## Sponsor details

CRC and UCL Cancer Trials Centre 222 Euston Road London United Kingdom NW1 2DA +44 (0)20 7679 8060 bnli@ctc.ucl.ac.uk

## Sponsor type

Charity

#### Website

http://www.bnli.ucl.ac.uk

# Funder(s)

## Funder type

Research organisation

## Funder Name

British National Lymphoma Investigation (BNLI) (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?
Results article	results	18/05/2009		Yes	No