

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

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/09/2019	Condition category 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

Dr - -

Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00005867

Protocol serial number

GOOD RISK

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

Study type(s)

Treatment

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

Not Specified

Drug/device/biological/vaccine name(s)

Various

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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 Or 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 ≥ 10 g/dL Neutrophils $\geq 2 \times 10^9$ /L Platelets $\geq 100 \times 10^9$ /L
6. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

18 years

Upper age limit

59 years

Sex

All

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

United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
British National Lymphoma Investigation (BNLI) (UK)

Funder(s)

Funder type
Research organisation

Funder Name
British National Lymphoma Investigation (BNLI) (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	18/05/2009		Yes	No