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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 27/09/2019	**Condition category** 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
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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 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 ≥10 g/dL Neutrophils ≥2 x 10^9/L Platelets ≥100 x 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