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

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

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)

Primary study design
Interventional

Study design
Randomised controlled trial

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