

CHOP versus PMItCEBO with/without G-CSF in patients aged sixty years plus with 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 22/10/2018	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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 measure

Failure free survival

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/1996

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

Age group

Senior

Sex

Both

Target number of participants

Planned sample size: 880

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**

England

United Kingdom

Study participating centre

90 Tottenham Court Road

London

United Kingdom

W1T 4TJ

Sponsor information**Organisation**

Lymphoma Research Trust (UK)

Sponsor details

Trustees Department

5th Floor East

250 Euston Road

London

United Kingdom

NW1 2PG

Sponsor type

Charity

Website

<http://www.lymphoma-research-trust.org.uk/>

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Lymphoma Research Trust (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?
Plain English results				No	Yes
Results article	results	18/05/2009		Yes	No