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Trial of CHOP versus CIOP in Good Risk Stage II-IV 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 31/10/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LY/GR

Study information

Scientific Title
Trial of CHOP versus CIOP in Good Risk Stage II-IV Patients with Histologically Aggressive Non-Hodgkin's Lymphoma

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
Patients are randomised to one of two treatment regimens:
1. CHOP Regimen: Adriamycin, cyclophosphamide, vincristine and prednisone cycle repeated every 3 weeks. Chemotherapy to be given for two courses beyond complete remission and a minimum of six courses or until progression.
2. CIOP Regimen: Idiarubicin, cyclophosphamide, vincristine and prednisone cycle repeated every 3 weeks. Chemotherapy to be given for two courses beyond complete remission and a minimum of six courses or until progression.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1995

Completion date
14/07/1997

Eligibility

Key inclusion criteria
1. Age 16-59 years
2. No medical conditions, other than lymphoma, prohibiting intensive therapy and no systemic treatment for cancer in previous 5 years
3. One of the following histological types:
3.1 Follicular large cell
3.2 Diffuse mixed cell
3.3 Diffuse large cell
3.4 Diffuse immunoblastic lymphomas
4. Full clinical staging to include Computed Tomography (CT) scanning of abdomen and bone marrow trephine biopsy
5. Good prognostic features defined as the presence of less than two of:
5.1 Stage III/IV
5.2 Lactic dehydrogenase (LDH) >normal
5.3 Eastern Cooperative Oncology Group (ECOG) or World Health Organisation (WHO) performance status 2-4

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Total final enrolment
211

Key exclusion criteria

Not provided at time of registration

Date of first enrolment
01/01/1995

Date of final enrolment
14/07/1997

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
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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

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	01/08/2005	31/10/2019	Yes	No