

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
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/10/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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: Idarubicin, 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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

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

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