

A randomised trial of radiotherapy alone versus three cycles of cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) chemotherapy plus radiotherapy versus six cycles of CHOP chemotherapy plus radiotherapy for early stage aggressive non-Hodgkin's lymphoma

Submission date 01/07/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/11/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

Study information

Scientific Title

A randomised trial of radiotherapy alone versus three cycles of cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) chemotherapy plus radiotherapy versus six cycles of CHOP chemotherapy plus radiotherapy for early stage 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

Non-Hodgkin's lymphoma

Interventions

Patients are randomised to one of three treatment regimens:

1. Regimen A: Radiotherapy 40 Gy in twenty to twenty-five fractions.
2. Regimen B: Chemotherapy with cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) repeated every 21 days for three cycles. Radiotherapy 30 Gy in fifteen fractions for patients in complete remission or 40 Gy in twenty to twenty-five fractions for patients who are not in chemotherapy induced complete remission.
3. Regimen B: Chemotherapy with cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) repeated every 21 days for six cycles. Radiotherapy 30 Gy in fifteen fractions for patients in complete remission or 40 Gy in twenty to twenty-five fractions for patients who are not in chemotherapy induced complete remission.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cyclophosphamide, doxorubicin, vincristine and prednisolone

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/10/1996

Eligibility

Key inclusion criteria

1. Biopsy-proven non-Hodgkin's lymphoma of any of the following histologies: International Working Formulation groups F, G and H; Kiel Classification: centroblastic B-cell, pleomorphic medium and large T-cell, immunoblastic, large cell anaplastic and high grade unclassified; Revised European-American Classification of Lymphoid Neoplasms (REAL Classification): Diffuse large B-cell, anaplastic large cell, high-grade B-cell or Mucosa-associated lymphoid tissue (MALT) type, and peripheral T-cell
2. WHO performance status 0, 1, 2
3. Aged greater than 15 years
4. No previous chemotherapy or radiotherapy
5. Normal lactic dehydrogenase (LDH)
6. Stage I, IE, II, IIE, except bulky abdominal presentation
7. No B symptoms
8. No previous malignancy, except basal cell carcinoma of the skin or cervical carcinoma stage I
9. No evidence of Human Immunodeficiency Virus (HIV) positively
10. No contraindications to protocol treatments

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex**Key exclusion criteria**

Patients with testicular, brain, gastrointestinal or skin primaries are excluded

Date of first enrolment

01/01/1990

Date of final enrolment

31/10/1996

Locations

Countries of recruitment

United Kingdom

Study participating centre

-

-

United Kingdom

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Sponsor information

Organisation

Cancer Research UK (CRUK) (UK)

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary