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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	[_] Prospectively registered [_] Protocol
Registration date 01/07/2001	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 21/11/2019	**Condition category** Cancer	[_] Individual participant data [_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LY05

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 cylophosphamide, 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 cylophosphamide, 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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1990

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

Age group

Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
-

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
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WC2A 3PX
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Sponsor type
Charity

Website
http://www.cancer.org.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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