ISRCTN55593137 https://doi.org/10.1186/ISRCTN55593137

# 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

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|---|---|---|
| **Submission date**<br>01/07/2001 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>01/07/2001 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>21/11/2019 | **Condition category**<br>Cancer | [_] Individual participant data<br>[_] 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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kate.law@cancer.org.uk

**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