

# A randomised study comparing weekly alternating chemotherapy with three-weekly chemotherapy in advanced high grade non-Hodgkins lymphoma

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/02/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

**Contact name**  
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**Contact details**  
UKCCCR Register Co-ordinator  
MRC Clinical Trials Unit  
222 Euston Road  
London  
United Kingdom  
NW1 2DA

## Additional identifiers

**Protocol serial number**  
NH3001

## Study information

**Scientific Title**

A randomised study comparing weekly alternating chemotherapy with three-weekly chemotherapy in advanced high grade non-Hodgkins 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

### **Primary study design**

Interventional

### **Study design**

Randomised controlled trial

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Lymphoma (non-Hodgkin's)

### **Interventions**

1. Regimen CAPOMET: Combination chemotherapy with CAPOMET (cyclophosphamide, adriamycin, prednisolone, vincristine, methotrexate and etoposide). A weekly regimen repeated every 4 weeks with the more myelotoxic combinations cyclophosphamide and adriamycin, methotrexate and etoposide alternating with the more marrow sparing combination prednisolone and vincristine, but ending with cyclophosphamide and adriamycin. Chemotherapy should be continued until complete remission plus 8 weeks with a minimum of 12 weeks of treatment.

2. Regimen CHOP-Methotrexate: Three weekly cycle of combination chemotherapy, CHOP-methotrexate (cyclophosphamide, adriamycin, prednisolone, vincristine and methotrexate) repeated until complete remission plus three cycles for a minimum of five cycles.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

CAPOMET (cyclophosphamide, adriamycin, prednisolone, vincristine, methotrexate and etoposide), CHOP-methotrexate (cyclophosphamide, adriamycin, prednisolone, vincristine and methotrexate)

### **Primary outcome(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/12/2000

## Eligibility

**Key inclusion criteria**

1. High grade pathology, malignant lymphoma classified as: Centroblastic; Lymphoblastic; Immunoblastic; True histocytic; High grade unclassified
2. Advanced (stage III or IV, extensive abdominal or otherwise bulky stage II disease)
3. No specific age limit but considered able to tolerate either treatment regimen
4. No previous radiotherapy, chemotherapy or immunotherapy
5. No previous malignancy, except adequately treated basal cell carcinoma or in-situ carcinoma of cervix
6. No serious medical or psychological condition precluding adequate treatment
7. Able to tolerate daily fluid intake of at least 2 litres
8. Ability of participating clinician to support patients with severe marrow hypoplasia

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex****Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2000

**Date of final enrolment**

31/12/2000

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**MRC Clinical Trials Unit**

London

United Kingdom

NW1 2DA

## **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**