A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials			Date of birth	(dd/mm/yyyy)
Centre			Consultant	
Sex		1=M, 2=F		

To randomize a patient please fax completed form to 0207 679 8061. For queries please call The Lymphoma Trials Office 0207 679 8060.

Registration form (page 1 of 6)

Eligibility checklist

	Inclusion criteria	**Yes**	**No**
1	Age ≥18 years		
2	Histologically proven diffuse large B-cell lymphoma, anti CD20 positive		
3	No previous chemotherapy, radiotherapy or other investigational drug for this indication		
4	Bulky stage IA (defined as lymph node or lymph node mass greater than 10cm in diameter), IB, stage II, stage III and IV		
5	WHO performance status 0-2		
6	Adequate bone marrow function with platelets $>100x10^9$/l; neutrophils $>1.5x10^9$/l at the time of study entry unless attributed to bone marrow infiltration by lymphoma		
7	Serum creatinine <150μmol/l, serum bilirubin <35μmol/l and transaminases <2.5upper limit of institutional normal range unless attributed to lymphoma		
8	Normal MUGA or echocardiogram without any areas of abnormal contractility and acceptable left ventricular ejection fraction (LVEF) ≥50% (only applicable if aged over 70, known diabetic over 65, past history of cardiac disease or hypertension or abnormal resting ECG)		
9	No concurrent uncontrolled medical condition		
10	No active malignant disease other than basal or squamous cell carcinoma of the skin or carcinoma in situ of the uterine cervix in the last 10 years		
11	Life expectancy >3 months		
12	Adequate contraceptive precautions for all patients of child bearing potential		
13	Written, informed consent		

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Eligibility checklist

	Exclusion criteria	**Yes**	**No**
1	T-cell lymphoma or transformed follicular lymphoma		
2	Previous history of treated or non-treated indolent lymphoma. However patients not previously diagnosed who have a diffuse large B-cell lymphoma with some small cell infiltration in bone marrow or lymph node may be included		
3	Past history of heart failure or uncontrolled angina pectoris		
4	Central nervous system, meningeal involvement or cord compression by the lymphoma		
5	Cardiac contra-indication to doxorubicin (abnormal contractility on echocardiography or nuclear medicine examination (MUGA))		
6	Neurological contra-indication to vincristine (e.g. pre-existing diabetic neuropathy)		
7	Any other serious active disease		
8	General status that does not allow the administration of 8 courses of CHOP according to the investigator		
9	Positive serology for HIV, Hepatitis B or Hepatitis C		
10	Medical or psychiatric conditions that compromise the patients ability to give informed consent		

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Registration form (page 3 of 6)

Pre-treatment assessment

Date of assessment		(dd/mm/yyyy)
Date of diagnostic biopsy		(dd/mm/yyyy)
Height		(cms)
Weight		(kgs)
Body surface area		(m^2)
Stage		1= IA, 2=IB 3=II, 4=III, 5=IV
WHO performance status		0-2
B Symptoms		1=Absent, 2=Present
Bulky disease		1=Absent, 2=Present

Haematology

Date of haematology		(dd/mm/yyyy)	
	Value	**Units**	**Normal range**
Haemoglobin		g/dl	
Platelets		$x10^9$/l	
White blood cells		$x10^9$/l	
Neutrophils		$x10^9$/l	
Lymphocytes		$x10^9$/l	

Biochemistry

Date of biochemistry		(dd/mm/yyyy)	
	Value	**Units**	**Normal range**
Sodium		mmol/l	
Potassium		mmol/l	
Creatinine		μmol/l	
Urea		mmol/l	
Albumin		g/l	
Total protein		g/l	
Calcium		mmol/l	
Phosphate		mmol/l	
LDH		IU/l	
Bilirubin		μmol/l	
Alkaline phosphatase		IU/l	
AST		IU/l	
ALT		IU/l	
β2 microglobulin		mg/l	

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Registration form (page 4 of 6)

Pre-treatment assessment

Investigation	**Date** (dd/mm/yyyy)	**Result** 1=Normal 2=Abnormal, please specify 3= Not done
Chest x-ray		
Specify abnormality		
CT scan neck		
Specify abnormality		
CT scan chest		
Specify abnormality		
CT scan abdomen		
Specify abnormality		
CT scan pelvis		
Specify abnormality		
ECG		
Specify abnormality		
Echocardiogram		
Specify abnormality		
MUGA scan		
Specify abnormality		
CSF examination		
Specify abnormality		
Bone marrow aspirate		
Specify abnormality		
Bone marrow trephine		
Specify abnormality		

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Registration form (page 5 of 6)

Sites of Nodal Disease

Date of assessment		(dd/mm/yyyy)		
Site	**Involved** Y=Involved N= not involved	**Investigation** 1=clinical 2=x-ray 3=CT scan 4=other	**Measurable** M=measurable E=evaluable	**Size** Bidimensional measurements (mm x mm)
Left cervical				
Right cervical				
Left supraclavicular				
Right supraclavicular				
Waldeyer's ring				
Left axillary				
Right axillary				
Paratracheal				
Mediastinal				
Hilar				
Retrocrural				
Para-aortic				
Coeliac axis				
Mesenteric				
Splenic				
Portal				
Left iliac				
Right iliac				
Left inguinal				
Right inguinal				
Left femoral				
Right femoral				
Other, specify				
Other, specify				
Other, specify				
Other, specify				

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Centre			Consultant	
Sex		1=M, 2=F		

Registration form (page 6 of 6)

Sites of extranodal disease

Date of assessment		(dd/mm/yyyy)		
Site	**Involved** Y=Involved N= not involved	**Investigation** 1=clinical 2=x-ray 3=CT scan 4=other	**Measurable** M=measurable E=evaluable	**Size** Bidimensional measurements (mm x mm)
Spleen				
Liver				
Lungs				
Bone marrow				
Gastric				
Kidney				
Pericardium				
Pleura				
Skin				
Testis				
Other, specify				
Other, specify				

Form completed by: _____ Date of completion: _____

Signature: _____

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Centre			Consultant	
Sex		1=M, 2=F		

Randomisation form (page 1 of 1)

International Prognostic Index

Criteria	1=Yes, 0=No
Age >60 years	
Tumour stage III or IV	
WHO performance status ≥2	
Serum LDH greater than upper limit of local normal range	
More than one extranodal site	
Total IPI score	

Eligibility confirmation	Y=Yes, N=No
Does the patient fulfill all the eligibility criteria?	
Proof of written informed consent obtained	

Form completed by: _____ Date of completion: _____

Signature: _____

For office use only **If sections above are completed and patient is eligible, proceed with randomisation**	
Allocated trial number	
Arm A – R-CHOP21: CHOP for 8 cycles and rituximab for 8 cycles given every 21 days	
Arm B – R-CHOP14: CHOP for 6 cycles and rituximab for 8 cycles given every 14 days	
Randomised by	**Date randomised (dd/mm/yyyy)**