CANCER RESEARCH UK & UCL CANCER TRIALS CENTRE

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FAX MESSAGE
R-CODOX-M/IVAC TRIAL **A Phase II Single Arm Study of the use of CODOX-M/IVAC with Rituximab (R-CODOX-M/IVAC) in the treatment of patients with Diffuse Large B-Cell Lymphoma (DLBCL) or Burkitt's Lymphoma (BL) of International Prognostic Index High or High-Intermediate Risk**
REGISTRATION FORM
From: _____ **Centre:** _____ **Phone number:** _____ **Fax number:** _____ **Pharmacy Contact:** _____ **Pharmacy Fax number:** _____ **Date:** _____ **Please fax the Registration Form together with this cover sheet to the Trials Centre on:** **0207 679 9861** For queries please call The Haematology Trials Group on 0207 679 9860.
Total number of pages (including cover):

A Phase ll Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

Registration form (page 1 of 8)

Eligibility checklist

	Inclusion criteria	Yes	No	N/A
1	Histologically proven DLBCL and all morphological variants or Burkitt's lymphoma (BL), according to the current WHO classification. The B cell nature of the proliferation verified by the positivity with an anti-CD20 antibody			
2	Age 18-65 years (inclusive)			
3	IPI score high intermediate (score=3) or high (score=4,5). IPI defined as Age greater than 60 years, stage lll or lV, raised LDH, more than 1 extranodal site and poor performance status – WHO performance status $\geq$2. (Protocol Appendix 1)			
4	No previous chemotherapy, radiotherapy or other investigational drug for this indication **(although pre-treatment with steroids is acceptable)**			
5	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			
6	Serum creatinine < 150µmol/l, serum bilirubin < 35µmol/l and transaminases < 2.5x upper limit of institutional normal range unless attributed to lymphoma (AST/ALT)			
7	Echocardiogram or nuclear medicine scan (MUGA) should be performed if past history of diabetes, cardiac disease, hypertension or abnormal resting ECG. **An ECHO or MUGA is mandatory for all patients aged 61 - 65 years inclusive, and the Left Ventricular Ejection Fraction (LVEF) should be normal according to local ranges.**			
8	No concurrent uncontrolled medical condition			
9	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			
10	Life expectancy > 3 months			
11	Disease stage II – IV			
12	Adequate contraceptive precautions for all patients of childbearing potential (during treatment and at least 12 months after treatment)			
13	Signed consent form			
14	If patient has HIV positive serology only one or none of the following criteria may apply **(please tick one only, if applicable)**			
	CD4 count less than 100/_L			
	Prior history of opportunistic infections			
	Karnofsky performance score (KPS) less than 60 or ECOG score >2			

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	Exclusion criteria	**Yes**	**No**
1	Disease stage I		
2	T-cell lymphoma		
3	Previous history of treated or non-treated indolent lymphoma. However, diffuse large B cell patients not previously diagnosed who have large B-cell lymphoma with some small cell infiltration in bone marrow or lymph node may be included		
4	Past history of heart failure or uncontrolled angina pectoris		
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 2 cycles of CODOX-M/IVAC according to the investigator		
9	Patients with a positive serology for HIV not satisfying the criteria in Inclusion Criteria, Hepatitis B or Hepatitis C		
10	Medical or psychiatric conditions that compromise the patient's ability to give informed consent		

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Pre-treatment assessment

Date of assessment	/ /	(dd/mm/yyyy)
Age		Years
Stage		II, III or IV
Diagnosis		1=DLBCL, 2=BL
WHO performance status		0-4
B Symptoms		1=Absent, 2=Present
Bulky disease		1=Absent, 2=Present
Proven CNS Disease		1=Yes, 2=No
Karnofsky Performance Score		0-60
ECOG score		0-4

Haematology

	Value	**Units**
Date of haematology	/ /	(dd/mm/yyyy)
Haemoglobin		g/dl
Platelets		$x10^9/l$
White blood cells		$x10^9/l$
Neutrophils		$x10^9/l$
Lymphocytes		$x10^9/l$
CD4		(100/_L)

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Biochemistry

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

Serology

	Date (dd/mm/yyyy)	**Result** 1=Negative 2=Positive
HIV	/ /	
HBV	/ /	
HCV	/ /	

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Pre-treatment assessment

Investigation	**Date** (dd/mm/yyyy)	**Result** 1=Normal 2=Abnormal
CT scan thorax	**/ /**	
CT scan abdomen	**/ /**	
CT scan pelvis	**/ /**	
Investigation	**Date** (dd/mm/yyyy)	**Result** 1=Normal 2=Abnormal 3=Not done
CT scan neck	**/ /**	
Electrocardiogram	**/ /**	
Specify abnormality		
Echocardiogram	**/ /**	
LVEF		**%**
Specify abnormality		
CSF examination	**/ /**	
Specify abnormality		
Bone marrow aspirate	**/ /**	
Specify abnormality		
Bone marrow trephine	**/ /**	
Specify abnormality		

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Investigation	**Date** (dd/mm/yyyy)	**Result** 1=Minimal residual uptake 2=positive disease 3=Not done
PET scan (if applicable)	**/ /**	

Sites of nodal disease

Site	**Involved** Y=Involved N=Not involved	**Investigation** 1=Clinical 2=X-ray 3=CT scan 4=PETscan, 5=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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Sites of extranodal disease

Site	**Involved** Y=Involved N=not involved	**Investigation** 1=Clinical 2=X-ray 3=CT scan 4=PET scan, 5=Other	**Measurable** M=measurable E=evaluable	**Size** Bidimensional measurements MM x MM
Liver				
Lungs				
Bone marrow				
Gastric				
Kidney				
Pericardium				
Pleura				
Skin				
Testis				
Other, specify				
Other, specify				

International Prognostic Index

Criteria	1=Yes, 0=No
Age greater than 60 years	
Tumour stage III or IV	
WHO performance status ≥ 2 (see Protocol Appendix 2)	
Elevated Serum LDH	
More than 1 extranodal site	
Total IPI Score	

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Histology

Date of diagnostic biopsy?		dd/mm/yyyy
Block number		

Informed consent

Part 1 of the consent form signed		1=Yes, 2=No
Part 2 of the consent form signed		1=Yes, 2=No
Date of informed consent	/ /	dd/mm/yyyy
Version & Date of consent form used		
Version & Date of Patient Information Sheet used		

Form completed by:	Date of completion:
Signature:	

For office use only

If sections above are completed and patient is eligible, proceed with registration

Allocated trial number	**RCM**
Registered by	**Date registered** (dd/mm/yyyy)