UKALL14 Trial Number 14 Patient Initials

FAX MESSAGE

POST INDUCTION REGISTRATION FOR TRANSPLANT INCLUDING PALIFERMIN RANDOMISATION

DATE (DD/MM/YYYY): ☐☐ ☐☐ ☐☐☐☐

ATTENTION: UKALL14 TRIAL TEAM

FAX No: 0207 679 9861

Number of pages (including cover sheet): ☐☐

Palifermin Randomisation must be completed prior to starting Myeloablative Conditioning

REGISTERING HOSPITAL:	
CONSULTANT:	
RESEARCH CONTACT:	
PHONE NO:	
FAX NO:	

TRANSPLANT HOSPITAL:	
CONSULTANT:	
RESEARCH CONTACT:	
PHONE NO:	
FAX NO:	
PHARMACY CONTACT:	
PHONE NO:	
FAX NO:	

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Registration for Transplant (1/4)

Answers to the following questions must be YES

Inclusion Criteria for TRANSPLANT		Yes	No
1	Completion of Phase 1 and Phase 2 induction treatment within the trial (in CR).		
Tick ONE of the answers below			
2a	HLA-compatible sibling donor?		
2b	Unrelated donor:(8/8 molecular match at A,B,C & DR. DQ mismatch is permitted) **Patients with matched unrelated donors must be HIGH RISK to proceed to transplant. Please complete HIGH RISK inclusion criteria below**		
2c	Unrelated donor:(7/8 MMUD/umbilical cord unit) **Patients with mismatched unrelated donors must be HIGH RISK on cyto-genetics or MRD to proceed to transplant. Please complete HIGH RISK inclusion criteria below**		

Answers to the following questions must be NO

Exclusion Criteria for TRANSPLANT		Yes	No
1	Relapsed disease.		
2	Standard risk patient without a sibling donor (these patients will continue chemotherapy consolidation and maintenance).		

Inclusion Criteria for HIGH RISK ARM - unrelated donor stem cell transplantation

Any one of the factors below makes the patient high-risk: (1=Yes, 2=No)

Over 40 years of age ☐

WBC: ≥30 x 10^9/L (precursor-B cell ALL) OR ≥100 x 10^9/L (T-cell ALL) ☐

Cytogenetics

t(4,11)(q21;q23)/*MLL-AF4* ☐

Low hypodiploidy/near triploidy (30-39 chromosomes/60-78 chromosomes) ☐

Complex karyotype (five or more chromosomal abnormalities) ☐

Philadelphia chromosome t(9;22) (q34;q11)/BCR-ABL1 ☐

High risk Minimal Residual Disease (MRD) post Phase 2 Induction ☐

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Registration for Transplant (2/4)

Pre-Transplant Evaluations

The following assessments must be performed prior to transplantation of a patient:

Date of Assessment (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

Please enter the result for the following pre-transplant evaluations:

Karnofsky Score ☐☐☐ %

ECOG Performance Status ☐

Comorbidity Index ☐☐ *Please also complete page 3*

Patient CMV status
(1= positive 2= negative) ☐

Proposed start date of Conditioning Regimen (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

Transplant Centre

Is the patient moving to a different centre for their transplant? (1=Yes, 2=No) ☐

If yes, Please answer the questions below:

Centre:

Contact:

Please specify which treatment phases will be carried out at the Transplant Centre (circle all that apply): Intensification / Conditioning / Transplant (until discharge from in-patient stay) / Post Transplant Assessment (6/9/12/18/21/24 months)

If the patient is being transferred permanently to the Transplant Centre, please complete a Centre Transfer Form.

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Registration for Transplant (3/4)

Pre-Transplant Evaluations - Comorbidity Index

Please specify the comorbidities present: (1=Yes, 2=No)

Comorbidity	Definition	Score	Comorbidity present?
Arrhythmia	Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias	1	
Cardiac	Coronary artery disease, congestive heart failure, myocardial infarction, or EF≤50%	1	
Inflammatory bowel disease	Crohn's disease or ulcerative colitis	1	
Diabetes	Requiring treatment with insulin or oral hypoglycaemic, but not controlled with diet alone	1	
Cerebrovascular disease	Transient ischaemic attacks or cerebrovascular accident	1	
Psychiatric disturbance	Depression/anxiety requiring psychiatric consult and/or treatment at the time of transplant	1	
Hepatic (mild)	Chronic hepatitis, Bilirubin >ULN to 1.5xULN, or AST/ALT>ULN to 2.5xULN	1	
Obesity	BMI>35	1	
Infection	Documented infection or fever of unknown aetiology requiring antimicrobial treatment before, during and after the start of conditioning regimen	1	
Rheumatological	SLE, RA, polymyositis, mixed CTD and polymyalgia rheumatica	2	
Peptic ulcer	Requiring treatment	2	
Renal (moderate/severe)	Serum creatinine>2mg/dL†, on dialysis or prior to renal transplantation	2	
Pulmonary (moderate)	DLCO and/or FEV_1 66-80% or dyspnoea on slight activity	2	
Prior solid tumour	Treated at any point in the patients history, excluding non-melanoma skin cancer	3	
Heart valve disease	Except asymptomatic mitral valve prolapse	3	
Pulmonary (severe)	DLCO and/or FEV_1 ≤65% or dyspnoea at rest or requiring oxygen	3	
Hepatic (moderate/severe)	Liver cirrhosis, bilirubin>1.5xULN, or AST/ALT> 2.5xULN	3	

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Registration for Transplant (4/4)

Transplant Registration & Palifermin Randomisation

Please indicate which transplant group patient is in:

1= Sibling donor & Non-myeloablative conditioning regimen

2= Sibling donor & Myeloablative conditioning regimen*

3= High Risk & Unrelated donor & Non-myeloablative conditioning regimen

4= High Risk & Unrelated donor & Myeloablative conditioning regimen*

Completed by:

Signature:

Date completed: d d m m y y y y

Transplant Registration for groups 1 & 3 above (TO BE COMPLETED BY UCL CTC):

Date of Registration to Transplant (dd/mm/yyyy)

Confirmed by (UCL CTC)

***PALIFERMIN Randomisation Result <u>for groups 2 & 4 above</u> (TO BE COMPLETED BY UCL CTC):**

For patients proceeding to transplant who are ≤ 40 years of age at study entry and being treated with the Myeloablative Conditioning regimen.

<u>Key:</u>
Dose of Palifermin:
P1 = Standard
P2 = Collapsed

Date of Randomisation (dd/mm/yyyy)

Registered/Randomised by (UCL CTC)