UKALL14 | Trial Number: 14 | Patient Initials:

Induction Treatment—Phase 1 Form (1/6)

Steroid Pre-Phase

Was treatment given according to protocol schedule (i.e. for 5-7 days, without dose reduction, delay or omission)? (1=Yes, 2=No) ☐

How many days of steroid pre-phase treatment were given? ☐

If No, please complete the table below:

Drug	Reduction[1]	Delay[1]	Omission[1]
Dexamethasone			

[1] 0=No reduction/delay/omission, 1=Neurotoxicity, 2=Hepatotoxicity, 3=Cardiotoxicity 4=Haematological Toxicity, 5=Infusion-related toxicity 6=Pancreatitis 7=Patient Choice, 8=Clinician Choice, 9=Administrative, 10=Other (specify below):

10 = OTHER Reason for Reduction/Delay/Omission

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UKALL14 Trial Number 14 Patient Initials

Induction Treatment—Phase 1 Form (2/6)

Phase 1 Induction - Standard Therapy

Date Phase 1 induction started (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

Was treatment given according to protocol schedule (i.e. without dose reduction, delay or omission)? (*1=Yes, 2=No)* ☐

If No, please complete the table below:

Drug	Reduction[1]	Delay[1]	Omission[1]
Daunorubicin			
Vincristine			
Dexamethasone			
Methotrexate			
Imatinib (for Ph+ve patients only)			

[1] 0=No reduction/delay/omission, 1=Neurotoxicity, 2=Hepatotoxicity, 3=Cardiotoxicity 4=Haematological toxicity, 5=Infusion-related toxicity 6=Pancreatitis 7=Patient choice, 8=Clinician choice, 9=Administrative, 10=Other (specify below):

Drug	10 = OTHER Reason for Reduction/Delay/Omission

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Induction Treatment—Phase 1 Form (3/6)

Phase 1 Induction - B Lineage/Rituximab Randomisation:

This page is to be completed for patients with B-lineage disease ONLY.

Randomisation Result: ☐

B1 = Standard Phase 1 Induction Alone
(do not complete the remainder of this page)
B2 = Standard Phase 1 Induction + Rituximab (R)

BSA (m^2) ☐

Day	Rituximab Dose (mg)	Reduction[1]	Delay[1]	Omission[1]
3				
10				
17				
24				

[1] 0=No reduction/delay/omission, 1=Neurotoxicity, 2=Hepatotoxicity, 3=Cardiotoxicity 4=Haematological toxicity, 5=Infusion-related toxicity 6=Pancreatitis 7=Patient choice, 8=Clinician choice, 9=Administrative, 10=Other (specify below):

10 = OTHER Reason for Reduction/Delay/Omission

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Induction Treatment—Phase 1 Form (4/6)

Oncaspar (Pegylated-Asparaginase)

BSA (m^2)

If the patient experienced a hypersensitivity reaction to Oncaspar, please indicate this in the 'omission' column in the table below, and then complete the Erwinase section of this page.

Day	Oncaspar Dose (IU)	Reduction[1]	Delay[1]	Omission[1]
4				
18				

[1] 0=No reduction/delay/omission, 1=Neurotoxicity, 2=Hepatotoxicity, 3=Cardiotoxicity 4=Haematological toxicity, 5=Infusion-related toxicity 6=Pancreatitis 7=Patient choice, 8=Clinician choice, 9=Administrative, 10=Other (specify below), 11=Hypersensitivity (switched to Erwinase), 12=Ph+ve

Day	10 = OTHER Reason for Reduction/Delay/Omission
4	
18	

Erwinase

If the patient experienced a hypersensitivity reaction to Oncaspar, and received Erwinase as an alternative, please complete the table below.

Planned Oncaspar Dose	Number of doses given	Total daily dose given (IU)
Day 4		
Day 18		

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UKALL14 Trial Number 14 Patient Initials

Induction Treatment—Phase 1 Form (5/6)

Liver Function Tests

Please enter liver function test results taken from routine bloods prior to/and after the doses of Oncaspar, if available.

Day 4– Prior to Oncaspar

Albumin (g/L) ☐☐☐ Bilirubin (µmol/L) ☐☐☐

Aspartate Transaminase (IU/L) ☐☐☐ Alanine Transaminase (IU/L) ☐☐☐

Day 4– Post Oncaspar

Albumin (g/L) ☐☐☐ Bilirubin (µmol/L) ☐☐☐

Aspartate Transaminase (IU/L) ☐☐☐ Alanine Transaminase (IU/L) ☐☐☐

Day 18– Prior to Oncaspar

Albumin (g/L) ☐☐☐ Bilirubin (µmol/L) ☐☐☐

Aspartate Transaminase (IU/L) ☐☐☐ Alanine Transaminase (IU/L) ☐☐☐

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UKALL14 | Trial Number: 14 | Patient Initials:

Induction Treatment—Phase 1 Form (6/6)

Response Assessment

To be completed post recovery from Phase 1 or at day 35, whichever is earlier

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

Days of neutrophils below 0.75 x 10^9/L ☐☐ Days of platelets below 75 x 10^9/L ☐☐

Number of days patient in hospital ☐☐

Bone Marrow Examination *To be performed following recovery from phase 1 induction*

Date of Bone Marrow Examination (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

Cellularity Grade ☐ (1=hypo, 2=normo, 3=hyper) % Blasts ☐☐☐

CSF examination

Does the patient have documented CNS disease? 1(=Yes, 2=No) ☐ *If yes, please complete below:*

Date of CSF examination ☐☐ ☐☐ ☐☐☐☐ Blast count/µL ☐☐☐☐

Local investigator's assessment of the patient's remission status

Remission Status ☐ 1=Complete remission 2=Not in remission

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

White Blood Cell Count x10^9/L ☐☐☐.☐☐

Neutrophils x 10^9/L ☐☐.☐☐

Haemoglobin g/dL OR g/L (circle units) ☐☐☐.☐

% blasts ☐☐☐

Platelets x 10^9/L ☐☐☐☐

Completed by:

Signature:

Date completed: d d m m y y y y

Please return to: UKALL14 Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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