UKALL14

Patient Information Version History

Trial Name	A randomised trial for adults with newly diagnosed acute lymphoblastic leukaemia
Chief Investigator	Dr Adele Fielding
EudraCT Number	2009-012717-22
REC Name	London – Fulham REC (formally Charing Cross REC)
REC Reference	09/H0711/90
REC Approval Date (Final)	13.01.2010

Key: superseded versions = grey rows |current versions = white rows

Document (PIS, Consent Form, GP Letter)	**Version Number**	**Version Date**	**Main Changes**	**REC Approval Date**	**MHRA Approval Date**	**Date of distribution to sites**
PATIENT INFORMATION SHEET						
PIS	1.0	11.11.2009	N/A	N/A	N/A	N/A
PIS	2.0	24.12.2009	Addition of flowchart to show standard treatment and trial treatment, as requested by the REC	13.01.2010	13.01.2010	19.01.2010
PIS	2.1	17.05.2010	Addition of funding/free drug information	07.06.2010	21.06.2010	23.06.2010
PIS	3.0	18.08.2010	Removal of Epratuzumab	08.09.2010	17.09.2010	22.09.2010
PIS	4.0	01.08.2012	Inclusion of more detailed pregnancy information from new UCL-CTC protocol template	23.08.2012	27.09.2012	08.10.2012
PIS	4.1	16.05.2013	Updated information on Rituximab relating to SJS and TENS – New safety information released by Roche	17.05.2013	N/A – Non-Substantial	20.05.2013
PIS	5.0	13.03.2014	Updated information on Rituximab relating to HBV/HCV reactivation – Updated safety information on Pegylated Asparaginase. Rewording of Nelarabine safety information	02.04.2014	N/A – Non-Substantial	02.04.2014
PIS	5.1	16.06.2014	Removal of the word 'slight' from the following paragraph: Allergic reactions: You may have an ~~slight~~ allergic reaction to rituximab	24.06.2014	15.07.2014	24.07.2014
PIS	5.2	29.04.2015	PIS amended to provide clarification of the following: - Sharing of limited patient identifiers (DOB, NHS number & initials) with external laboratories (required for invoicing and other logistical purposes) - To reflect move of central laboratory to UCL Cancer Institute - To reflect change in supplier of Nelarabine to Novartis following a recent take-over - Correction to schedule for nelarabine - Minor typographical corrections	21.05.2015	N/A – Non-Substantial	26.05.2015
PIS	5.3	09.09.2015	PIS amended to provide clarification of the following: • Clarification of age group intended to receive non-myeloablative	30.09.2015	15.11.2015	02.12.2015

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			transplant • Collaboration with EIRE will not be going ahead as originally planned • Clarification that the patients will have sequential tests following transplant that may impact on their disease management. • Clarification of the patient group intended to participate in the palifermin randomisation • Clarification of what is involved in the consolidation and maintenance phases of treatment • Clarification about the potential severity of nelarabine neurotoxicity; Standardisation of format of potential toxicity into list form • Administrative changes			
PIS	6.0	12.06.2016	• Amended to reflect the closure of the palifermin randomisation • New paragraph added regarding GRAALL data – Added to reflect some new evidence that recently came to light at a scientific conference in December 2015. • Various minor administrative changes	06.06.2016	15.06.2016	21.06.2016
PIS	7.0	17.02.2017	• Recruitment total updated from 720 to 811 • Clarification that chimerism and MRD samples should be sent to two separate locations	09.03.2017	n/a	20.03.2017
PIS	8.0	09.08.2017	• Clarification that pegylated asparaginase & nelarabine can both cause confusion and drowsiness. Warning added to avoid driving and operating machinery.	05.09.2017	n/a	07.09.2017
PIS	9.0	11.09.2017	• Clarification that chimerism testing is a standardised test performed after transplant. • That chimerism testing will be performed locally and result sent to UCL CTC.	30.10.2017	21.11.2017	01.12.2017
PIS	10.0	28.06.2018	• Clarification that copy of cytogenetics report will be sent to Newcastle University (LRCG). • Clarification that left over cells may be sent to LRCG for further analysis • Update to indicate oral contraception is not the best option, patient to speak with GP • Update on side effects of pegylated asparaginase • Clarification about personal information as per GDPR	14.08.2018	31.08.2018	30.07.18 with HRA categorisation email. 12.09.18 approvals distributed
'REGISTRATION ONLY' PIS (includes Consent form created as one document)						
'Registration only' PIS	1.0	24.05.2017	New document	n/a	Amendment rejected	Never distributed

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'Registration only' PIS	1.1	26.06.2017	REC felt that the amendment was on the borderline of requiring an application as a new study, however, they were happy to provide a favourable opinion, subject to updating the PIS; in the paragraph under the heading, "Who has reviewed the trial?" it should be "formerly", rather than "formally"…	05.07.2017	n/a	Never distributed
'Registration only' PIS	2.0	11.09.2017	Updated to reflect the MHRA recommended Sub-study format	30.09.2017	n/a	01.12.2017
'Registration only' PIS	3.0	28.06.2018	• Clarification that copy of cytogenetics report will be sent to Newcastle University (LRCG). • Clarification that left over cells may be sent to LRCG for further analysis • Clarification about personal information as per GDPR	14.08.2018	31.08.2018	30.07.18 with HRA categorisation email. 12.09.18 approvals distributed
GENETIC TESTING PIS						
Genetic testing PIS – Buccal Swab	1.0	09.09.2015	New document	30.09.2015	15.11.2015	02.12.2015
Genetic testing PIS – Bone Marrow	1.0	09.09.2015	New document	30.09.2015	15.11.2015	02.12.2015
ADDITIONAL PIS – SUSPENSION OF PALIFERMIN RANDOMISATION						
Additional PIS – Suspension of Palifermin	1.0	13.04.2016	New document	10.05.2016	n/a	03.06.2016
ADDITIONAL PIS – DRIVING & MACHINERY						
Additional PIS – Driving & Operating Machinery	1.1	31.08.2017	New document	05.09.2017	n/a	07.09.2017
PREGNANT PARTNER INFORMATION SHEETS						
Pregnant Partner PIS & Consent	1.0	17.05.2010	N/A	07.06.2010	21.06.2010	23.06.2010
Pregnant Partner PIS & Consent	1.1	18.08. 2010	Removal of Epratuzumab	08.09.2010	17.09.2010	22.09.2010
Pregnant Partner PIS & Consent	1.1	18.08. 2010	WITHDRAWN and replaced by Pregnancy Monitoring Information Sheet (Partner) v1.0 01.08.2012 & Pregnancy monitoring Consent Form (Partner) v1.0 01.08.2012	N/A	N/A	N/A
Pregnancy Monitoring Consent	v 1.0	01.08.2012	New templates released for use at the CRUK & UCL Cancer Trials Centre.	23.08.2012	27.09.2012	08.10.2012

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Form (Partner)						
Pregnancy Monitoring Consent Form (Patient)	v 1.0	01.08.2012	New template released for use at the CRUK & UCL Cancer Trials Centre.	23.08.2012	27.09.2012	08.10.2012
Pregnancy Monitoring Information Sheet (Partner)	v 1.0	01.08.2012	New template released for use at the CRUK & UCL Cancer Trials Centre.	23.08.2012	27.09.2012	08.10.2012
Pregnancy Monitoring Information Sheet (Patient)	V1.0	01.08.2012	New template released for use at the CRUK & UCL Cancer Trials Centre.	23.08.2012	27.09.2012	08.10.2012
INFORMED CONSENT FORM						
ICF	1.0	11.11.2009	N/A	13.01.2010	13.01.2010	N/A
ICF	1.1	03.09.2010	Section from part 2 moved to part 1			
ICF	1.2	29.04.2015	ICF amended to explicitly document consent for NHS number, initials and date of birth to be shared with laboratories	21.05.2015	N/A – Non-Substantial	26.05.2015
GENETIC TESTING ICF						
Genetic testing ICF – Buccal Swab	1.0	09.09.2015	New document	30.09.2015	15.11.2015	02.12.2015
Genetic testing ICF – Bone Marrow	1.0	09.09.2015	New document	30.09.2015	15.11.2015	02.12.2015
GP LETTER						
GP Letter	1.0	11.11.2009	New document	N/A	N/A	N/A