



UCL

Winter Newsletter 2019

UKALL14

A randomized trial for adults with newly diagnosed acute lymphoblastic leukaemia

Staff Changes

As some of you already know Emma Lawrie, UKALL14 Trial Coordinator will be going on maternity leave from Friday 25 January 2019. A new replacement Trial Coordinator has been appointed but does not start until Monday 4 February.

During the transition time we have a back-up TC, Luana Moreira, who some of you may know for UKALL60+, and she can be contacted with any important trial issues, and our data managers, Lynda Micklewright and Emma Diggins are still available to be contacted with any other queries.

Please also ensure that the UKALL14 mailbox is copied in to all correspondence (ctc.ukall14@ucl.ac.uk)

As soon as we have confirmation of the new TC contact details we will circulate these to all sites along with an updated contacts list.

'Registration only' sub-study

The 'registration only' sub-study is now fully open to both B-cell and T-cell patients. Any new patient identified as having ALL can be registered to the trial if they meet the eligibility criteria as stipulated in protocol Appendix 1.

New 'registration only' patients do not receive any IMPs, the treatment they receive is decided by their treating clinician and any alterations, dose modifications or treatment related questions do not need to be raised with the UKALL14 trial team but should be discussed internally with your research team.

To date our recruitment has been very good, currently we have 81 B-cell patients and 6 T-cell patients. Thank you all for your hard work, please keep this up!

Please see reminders below:

- All 'registration only' sub-study information is documented within Protocol Appendix 1.
- Blood tests and samples must be taken before steroids are given.
- Patients must be registered on the trial before any ALL treatment starts (this does not include steroids).
- MRD samples must still be sent to the central MRD lab (UCL Cancer Institute) as per Section 8.3 Appendix 1 of the Protocol.
- Treatment is per the local clinician's choice therefore the patients receive hospital stock. No drug is considered as an IMP within the sub-study regardless of whether following the main UKALL14 treatment backbone.
- Please continue to use the Centre Transfer CRFs to notify us when a 'registration only' patient transfers hospitals, so we can make sure we request data from the correct hospital.
- Safety data; AEs, SAEs and pregnancies, do not need to be reported for 'registration only' patients.
- If a 'registration only' patient needs to start chemotherapy urgently, please let us know when you send the registration form through, so we can prioritise urgent registrations.

Incidents

As a reminder, please ensure any queries regarding incident reports are responded to as soon as possible. This is to ensure that we have accurate information about incidents and can agree appropriate corrective and preventative actions in a timely fashion.

Central Monitoring

As you know we circulate central monitoring requests to sites during the anniversary month of the site opening. We request return of various documentation for review and also provide checklists for sites to use to support their local processes for maintaining their files.

If you identify you are missing any documents please check the UCL CTC website in the first instance before asking the UKALL14 team, there are 67 sites so it can take a while to send out if everyone puts in a request.

Going forward we will be using the CM requests to collect in accountability and balance logs from sites to begin the reconciliation process for the IMP's now the randomised patients have completed treatment – please can you provide these promptly to avoid delays in performing this task.

Please can you make every effort to respond to the CM requests in a timely manner.

Frozen Plasma samples

For those sites who have been able to collect the optional plasma samples for the randomised patients and have kept them within their local freezers, thank you for the efforts in obtaining and storing these. We are investigating the courier options presently and will be organising for shipment of these in due course.

Due to the staff changes as indicated above we cannot provide further dates on when this will take place, but we hope to arrange for these to be couriered from site to the central MRD lab within the upcoming months.

MRD samples

Anonymisation:

Unfortunately the MRD lab are still receiving samples with a patient's full name. **Please can we remind you that all samples and documentation must be anonymised before sending to the lab.** The patients' have not consented for these details to be sent to the MRD lab.

If your patient has come off trial treatment and clinicians still wish to send MRD samples to the MRD lab, please include this information when sending samples and ensure they are processed/anonymised as per your local policy with regards to sending non-trial samples

Trial documentation

Current trial documents are available via the UCL CTC website (<http://www.ctc.ucl.ac.uk/>). We also keep the superseded documents on our website, so you can locate any old documents if they are identified as missing when you review your site files.

Some documents are password protected. Please contact the study team at UCL CTC and they will let you know the password.

UKALL14 Trial Team Contacts

General Enquiries:	 0207 679 9860  0207 679 9861
	 ctc.ukall14@ucl.ac.uk
Trial Coordinator:	Luana Moreira (temporary TC from 28 Jan 19 until new replacement starts early Feb)
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Data Managers:	Lynda Micklewright / Emma Diggines
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