

A randomized trial for adults with newly diagnosed acute lymphoblastic leukaemia



Summer Newsletter 2018



'Registration only' sub-study

The 'registration only' sub-study opened to recruitment in December 2017, and we are recruiting B-cell patients at a good rate – thank you all for your hard work and please keep this up! We currently have 41 patients registered to the sub-study. Please see reminders below:

- All 'registration only' sub-study information is within Protocol Appendix 1
- 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 and no drugs are considered as IMPs (even if the clinician is following the 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, pregnancies) does not need to be reported for 'registration only' patients.
- We no longer routinely collect the start date of treatment as we did on the randomisation CRFs, but 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. .

T-cell recruitment

We have 4 more T-cell patients to randomise!

Please do remember to consider any new T-cell ALL patient for the trial.

We will be submitting a protocol amendment shortly to allow T-cell patients to also enter the 'registration only' sub-study once randomisation has closed, however we will update you on this nearer the time.

MRD samples

Anonymisation:

We have been made aware multiple times by the MRD lab that they 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.** The patient has not consented for these details to be sent to the MRD lab.

Shipment address:

We have also been made aware that some MRD samples have been incorrectly sent to the old MRD lab address at Royal Free Campus. Please ensure all MRD samples are sent to the MRD lab at **UCL Cancer Institute** and that the current sample request form is used (v5.0 23Nov2017), where the full address is also listed.

'Registration only' patients:

Please ensure that samples are taken and sent to the MRD lab, the process is the same as randomised patients.

If you have not taken/sent samples for 'registration only' patients please let us know immediately.

Data Management

We would like to welcome our new data manager, Emma Diggines, who joined the UKALL14 team in April. If you have any data related queries please do contact Emma or Lynda, as detailed in the contacts section below.

We would also like to take this opportunity to thank sites for your help and assistance in providing additional data for our recent EHA abstract, a copy of which is attached to this newsletter for your information.

Continuing on from this, we would be grateful for your continued help in responding to queries promptly as we work towards analysing the trial data.

Oncaspar drug orders

On 1st June Baxalta began supplying a new formulation of Oncaspar. Unlike the previous supply, this stock is licensed and as such you will no longer need to send the additional 'Unlicensed Medicinal Product form' when placing an order.

Please ensure that you check/liase with your pharmacy team when a new patient is identified to help ensure sufficient trial stocks and, where necessary, place an order promptly after patient has been consented for the randomised study to ensure a patient's dose is not missed.

Reminder:

All patients with trial numbers 14-1-XXX or 14-2-XXX are randomised patients. These patients get supplied IMP and orders are placed using trial specific drug order forms. All treatment for 'registration only' patients must be sourced from hospital supplies. Drug supplied for the trial MUST NOT be used to treat these patients.

N.B. oncaspar vials supplied for the trial look like standard commercial stock, therefore please ensure the product is segregated upon receipt.

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.

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.

UKALL14 Trial Team Contacts

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