Spring/Summer 2013 - Clinical Trial Update

New trials and studies.

IntReALL2010: an international trial for children (1-18 yrs) with relapsed acute lymphoblastic leukaemia (ALL) is opening across the UK, Ireland and ~18 other countries over the next few months. Guidelines for the standardisation of molecular cytogenetic analysis have been drawn up by cytogeneticists from all participating countries. A copy of these guidelines is included with this newsletter.

UKALL60+: a national study funded by the CRUK for older patients (60 years and over) with ALL. Cytogenetic data and material will be collected by the LRCG as per the current adult ALL trial, UKALL14. Please note there is no cytogenetic risk stratification in this study.

NCRI CCLG Childhood Leukaemia Cell Bank study: All children diagnosed with leukaemia are now being asked to consent to contribute samples to this national cell bank. Details can be found at www.cellbank.org.uk. This study is independent of any clinical trial. Many, but not all, patients who agree to the Cell Bank study will also be enrolled on a clinical trial. The Cell Bank study has consent to collect clinical and cytogenetic data in order to annotate the samples. Usually, these data will be collected via the clinical trial infrastructure. However, for non-trial patients other mechanisms are being put in place. The LRCG has agreed to collect cytogenetic data for these non-trial patients in the same way as for trial patients. However, there are two important differences: (1) we will not have permission to collect fixed cells from these non-trial patients; and (2) we will not know their final diagnosis. Therefore, we are designing new “non-trial” forms for you to provide us with the latest diagnostic information. As the Cell Bank has been operating for over a year now, there is a backlog of cases which we will be working through over the next 6 months.

On-going trials:

UKALL2011: This trial for children and young adults (1-24 years) with ALL has recruited >200 patients and virtually all sites are now open across the UK and Ireland. Patients with high risk cytogenetics [MLL gene rearrangement, near haploidy (23-29 chromosomes), low hypodiploidy (30-39 chromosomes), intrachromosomal amplification of chromosome 21 (iAMP21), and t(17;19)[q22;p13]] are being treated on regimen C and those with t(9;22)[q34;q11]/BCR-ABL1 are being transferred to an alternative protocol.

UKALL14: This national for adults (25-59 years) with ALL has recruited >200 patients. Patients with high risk cytogenetics are defined as those with Philadelphia chromosome / t(9;22)[q34;q11] / BCR-ABL1, t(4;11)[q21;q23]/MLL-AFF1, low hypodiploidy / near-triploidy (30-39/60-78 chromosomes) or a complex karyotype (five or more chromosomal abnormalities in the absence of an established translocation, abnormality or ploidy subgroup).

For both UKALL14 and UKALL2011, all trial related data (including high risk cytogenetics) are recorded on case report forms (CRF) by staff in the treating centre and then sent to the clinical trial unit (CTU). In order to minimise data interpretation errors, it would be helpful if you would please: (1) use the above terminology in the reports – the definition of complex karyotype is causing some confusion as it is mutually exclusive of established subtypes,such as high hyperdiploidy; and (2) differentiate between high risk cytogenetic abnormalities, which result in treatment changes, and those that have been associated with a poor prognosis. In addition, we will be cross-referencing cytogenetic data collected via the CRF with that we collect directly from you more regularly. Therefore, we will be chasing up outstanding data request forms more frequently. I hope you will agree that this double-check is vital and assist us by returning forms promptly. Please remember that we are more than happy to receive a copy of your cytogenetic report if that is more convenient than filling in the form.

If you have any questions regarding any of these trials or studies, please do not hesitate to contact Anthony Moorman (anthony.moorman@ncl.ac.uk)
Leukaemia Research Cytogenetics Group Newsletter

LRCG publications 2012-2013


