(Form to be on hospital/institution headed paper with CR UK logo included)

UKALL14: A randomized trial for adults with newly diagnosed acute lymphoblastic leukaemia

Patient Information Sheet: Additional genetic testing (buccal swab)

Version 1.0 09.09.2015

You have agreed to take part in the UKALL14 study. We would now like to invite you to take part in some additional research that is being carried out alongside the UKALL14 Study. Taking part in this extra research is optional and will not affect your taking part in the UKALL14 study.

Before you decide whether or not to take part, one of your doctor's team will go through this patient information sheet with you and answer any questions you may have so that you fully understand why we are carrying out this research and what it would involve for you.

Please take the time to read the information carefully and talk to others about the study if you wish. Ask us if there is anything you don't understand or if you would like more information and take your time to decide whether or not you wish to take part.

What is the purpose of the study?

The development of ALL is not well understood. More specifically the genetic changes that lead to the development of ALL have not been very well characterised.

Previous studies have looked at the genetic changes within leukaemic (cancerous) cells. They have shown us why some patients respond to treatment better than others. As part of your standard care and participation in the UKALL14 study your leukaemic cells were tested for 'cytogenetic abnormalities'.

The purpose of this study is to look at whether there are any genetic changes that ALL patients have in common in their non-leukaemic (non-cancerous) cells. This may help us understand why some adults develop ALL, but others do not.

Why have I been invited?

You have been invited to take part in the study because you have consented to take part in the UKALL14 study. This study is providing us with valuable data on how best to treat patients with ALL.

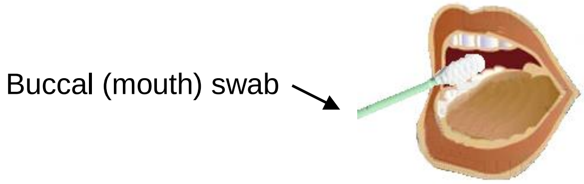
Do I have to take part?

No. It is up to you to decide whether or not to take part in the study. We will describe what would be involved and go through this patient information sheet with you, which is yours to take away so that you have the opportunity to read it carefully and discuss the study with others if you wish. If you decide to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. If you decide not to take part, or later to withdraw, this will not affect the standard of care you receive. It will also not affect your participation and treatment on the main UKALL14 study.

What will happen to me if I take part?

If you agree to take part, you will be asked to sign a consent form. By signing the consent form you are agreeing to provide a sample of cells that will be used to carry out genetic testing. In this case, the tests will look at your DNA, rather than the DNA of your leukaemic cells.

You will be asked provide a sample of cells from the inside of your cheek. This is done using a buccal (pronounced buckle) swab, which looks like a cotton bud.



The top of the swab is similar to the top of a cotton bud but firmer. It is used to rub the inside of your cheek to collect cells.

What will happen to any samples I give?

As explained above, we are asking you to donate a cheek swab. This sample will be sent to a central laboratory at the UCL Cancer Institute in London.

The sample will be labelled with a unique sample study and laboratory numbers. It will then be processed to isolate your DNA. We will then perform various genetic tests. The results of these tests will be studied alongside those of other ALL patients, to see whether we can identify genes that people who develop ALL have in common.

The results of tests performed will be held on a research database for use in medical research only. The results of your genetic testing will be linked with the genetic tests performed on your leukemic sample as part of the UKALL14 study.

Any extra material may be stored for use in future research which has been approved by an Ethics Committee. If you do not wish for this to be done, the sample will be disposed of in a way which meets the European Union regulations and directives for disposal of genetic material. You may withdraw your consent at any time, in which case the extra material will be destroyed.

What are the possible benefits of taking part?

The results of this genetic testing will not influence the treatment you are about to or have received. The information we get from this study will, however, help improve our understanding of with the link between genes and ALL in adults.

What will happen if I change my mind?

You can withdraw from the study at any time without giving reason. Any stored samples that can be identified as yours will be destroyed if you wish.

What will happen to the results of the tests?

We will not feedback the results found from the genetic tests to patients and their families. The results from the study will be made available to the public through scientific publications without disclosing your identity.

Thank you

Thank you for considering taking part in this study and for taking the time to read this patient information sheet, which is yours to keep. If you decide to take part in the study, you will also be given a copy of your signed consent form.