



ACCEPT

A phase Ib/II combination trial of acalabrutinib with rituximab, cyclophosphamide, doxorubicin, vincristine and prednisolone (R-CHOP) for patients with diffuse large B-cell lymphoma (DLBCL).

Request for permission to review your tumour sample

As you will have been told by your doctors, you have been found to have a type of non-Hodgkin's lymphoma known as diffuse large B-cell lymphoma. Once the usual tests and investigations have been completed, your specialist will meet with you to discuss the best form of treatment for you. In the meantime, we would like to ask your permission to perform a review of the biopsy that was taken to diagnose your lymphoma. This review will look at whether there is enough tissue in the sample in order for you to be eligible for a clinical trial called ACCEPT. You do not need to decide if you wish to take part in the trial at this point. If you do decide to take part then your tissue sample will be used to perform further tests to look at the pattern of genes that are active (or expressed) in your lymphoma, called gene expression profiling.

What is gene expression profiling?

Recent studies have suggested that there may be subtypes of diffuse large B-cell lymphoma that can be determined by studying the pattern of expression of genes that are active in the tumour. The expression of these genes may influence the response to chemotherapy.

What is the purpose of this review?

We would like you to consider taking part in a clinical research study (a clinical trial called ACCEPT). In this study an additional drug (called acalabrutinib) is being added to conventional chemotherapy (R-CHOP) to see if it improves the outcome of treatment. In order to be eligible for the study, we need to confirm that there is enough tissue in your diagnostic tumour biopsy to conduct the additional tests. If it is found that there is not enough tissue you will not be invited to take part in the study and your doctors will discuss with you the best alternative therapy.

Do I have to have the quantity of my lymphoma sample reviewed?

No. You can choose not to have your sample reviewed but it would mean that you cannot consider participation in the ACCEPT study. Your doctors will discuss alternative treatment options with you.

What will happen if I do agree to have my lymphoma sample reviewed?

If you agree to this review, then we will ask you to sign a consent form. The original consent form will be filed securely at the hospital. A copy of the consent form will be kept in your medical notes, a copy provided to you and a copy will be sent to the Southampton Clinical Trials Unit (SCTU), who are managing this study, via secure

email and held securely. We will arrange for the sample of your lymphoma to be taken out of storage and sent to the Haematological Malignancies Diagnostic Service (HMDS), in Leeds, along with a copy of your consent form. The SCTU will monitor the progress of your sample, using NHS systems, from your local hospital to the laboratory in Leeds to ensure that it is sent as soon as you have signed consent. The review of the quantity of tissue and the possible future gene expression profiling for this study is being performed in one laboratory. The gene expression profiling tests will only be done if sufficient tissue has been confirmed and you have agreed to participate in the ACCEPT study.

The review will remain strictly confidential at all times. Representatives of regulatory authorities, the trial sponsor and authorised NHS staff may need to review documentation to check that the review of your tissue is being carried out correctly. All of them have a duty of confidentiality to you as a research participant. Nothing that could reveal your identity will be disclosed outside of the research team.

A decision not to consent to have your tissue block reviewed will not affect the quality of care that you receive.

Does agreeing to the test mean that I have to take part in the ACCEPT study?

No. You may decide that you do not wish to take part in the ACCEPT clinical trial, in which case your doctors will discuss with you the best alternative therapy. If you decide not to participate in the ACCEPT study HMDS will return your tissue sample to your local hospital and not conduct any tests.

Additional Research

If there is sufficient tissue in your diagnostic tumour sample, the genetic profiling test will use only some of your lymphoma sample. The remaining tissue will be returned to your local hospital for storage.

The additional research that may be done with your tissue is not specifically designed to help you. It might however help people with lymphoma in the future. If your sample is used, this will be done in an anonymous way.

Will my details be kept confidential?

University Hospital Southampton NHS Foundation Trust is the sponsor for the ACCEPT study and are based in the United Kingdom. The sponsor and the Southampton Clinical Trials Unit (SCTU), who are acting on behalf of the sponsor, will act as the data controller for this study. This means that the sponsor and SCTU are responsible for looking after your information and using it properly.

You can find out more about how we use your information at
<https://www.southampton.ac.uk/ctu/about/index.page>.

Individuals who work at the Haematological Malignancy Diagnostic Service Lab (HMDS) will see your NHS number and signed consent form, as these must be sent along with the tissue samples that you give during your time on the trial for analysis. The reason for this is so that the lab can confirm that you have given your consent for them to review your sample. Your details would be stored electronically by HMDS along with your future tissue sample results, should you be eligible and decide to participate in ACCEPT, on their secure NHS servers. The paper copies of your consent form and NHS number are destroyed as confidential waste.

How do I find out more about ACCEPT?

Your doctor will discuss the ACCEPT clinical trial with you and what the alternatives are. You will have also received a patient information sheet which gives full details of what the study involves. You will have time to ask any questions that you may have.

Additional Information

We would like to encourage you to ask questions about the study until you are clear about what we intend to do. If you have more questions about the tissue quantity review or the ACCEPT study, please contact

Your doctor Tel:

Your research nurse Tel:

Thank you for taking the time to read this information sheet.