Precision medicine in laryngeal cancer: development of a laryngeal cancer cohort

Chief investigator – Mr David Hamilton

Dear Patient,

We would like to invite you to take part in the Laryngeal CAncer coHort (LARCH) research study. Before you decide if you want to take part, we would like you to understand why the research is being done and what it would involve for you.

Please take some time to read the following information carefully. We would encourage you to discuss your involvement with family, friends or your own GP. It is entirely your choice about whether to participate and you can change your mind at any time. Your future care will not be influenced by your decision.

This sheet will explain about the study and what will happen to you if you take part and will give more detailed information about the way the study will be conducted.

Please ask us if there is anything that is not clear, or if you would like more information (contact details for the research team are at the end of this information sheet).

Thank you for reading this.

What is the background to this study?

Cancer of the voice box (laryngeal cancer) is one of the most common head and neck cancers in the UK. There are many different ways to treat laryngeal cancer, and a lot of the treatments that we have available are very effective. However, most treatments have an effect on your quality of life and which is the best treatment for a patient is sometimes difficult to decide. You will also have an opinion on the treatment that you choose to receive.

What is the purpose of this study?

Through the course of this study we aim to collect information about you and your cancer in order to improve our knowledge about how laryngeal cancer patients are after their treatment. It will help us to understand which treatments are effective for which specific patients which will help us plan treatments for patients in the future.

Why have I been invited?

You have been invited as you have been diagnosed with laryngeal cancer, or we suspect that is what is going on. This means that your information can be helpful for our study.

Am I the only person involved in this study?

This study will invite over 150 patients who have a diagnosis of laryngeal cancer.

Do I have to participate?

Choosing to take part is completely up to you. If you choose to take part you will be asked to sign a consent form to confirm this. Even after this you are free to change your mind at any time and this will not affect your future care in any way.

What are the possible benefits of taking part?

There may not be any immediate benefits from taking part in the study. The information about you is collected and the study does not change in anyway the treatment that you receive. It will however help patients in the future.

What are the possible negative effects of taking part?

There are no specific negative effects of taking part. All the information that we collect are the tests which had done as part of your routine care. We will need you to fill out some questionnaires which might mean that you spend more time at your appointments

What will I have to do if I decide to take part?

If you agree to take part in this study, we will ask you to sign a consent form to confirm this. Your signature on this form indicates that you have understood the information regarding your participation in the research project and agree to participate. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without affecting your health care.

The LARyngeal Cancer coHort (LARCH)

If you choose to take part, and depending on which parts of the study you agree to take part in, then the information, tissue samples and scans that we collect as part of your routine care may be collected and recorded. Also, we will ask you to complete some questionnaires about your general health, quality of life, swallow and voice. We will ask you to repeat these questionnaires at various times through your treatment. You may be asked for a recording of your voice. Data that we might collect is shown in the table below and more detail is also given below:

Data collected	Reason for collection	Details
Clinical information about you and your cancer	We collect all this data about you routinely already	All data collected about you as part of your routine care will be recorded and stored separately
Scans	We already perform scans as part of your routine care	All scans will be stored and linked to the other data about you. The scans may be securely transferred to researchers elsewhere
Tissue/biopsies	We already take biopsies and perform surgical resections, but much of this tissue is discarded after it has been analysed	We may store any tissue that we take in a "biobank" and link it anonymously to other information about you. This means that researchers can carry out tests, linked to your data, to look for the causes of cancer or investigate new treatments. There may be tests of your genetic make up. The exact nature of these studies is not always known in advance but we would obtain approval from an independent research ethics committee prior to commencing the research. Your information and samples would contain only your unique study code and be anonymised such that any details that might identify you such as your name, date of birth, address, and hospital or NHS number were removed. You will not receive the results of any of these tests
Questionnaires	Performed as part of this research	You will be asked to complete questionnaires about your quality of life, swallow and voice straight away and at 6, 12 and 24 months after your diagnosis
Voice recordings	Performed as part of this research	These may be taken at diagnosis. You will not be identifiable from these voice recordings; they will be taken on a secure recorder and kept securely on a password protected computer. They may be transferred to other centres for other researchers to analyse
Future studies, long term storage and data linkage	Performed as part of this research	We will ask if we may contact you to inform you regarding future research studies that you may be suitable for. We will also ask if we may follow up what happens to you by accessing your medical notes and health related records over a long period of time. Examples of information may include attendances at hospital, whether you had cancer or other health conditions. Only certain authorised individuals from the study team will have access to this information. Your data will also be linked to routine data sources (such as Hospital Episode Statistics and mortality datasets) for data validation and long-term outcomes

Any data in the table above will be stored securely for a period of 20 years. Other researchers can apply to us to use these data to perform studies looking into the causes of laryngeal cancer or to investigate new ways of screening, diagnosing or treating laryngeal cancer. Data about you will only ever be shared with researchers from recognised research centres who have received ethical approval to conduct studies. All of the research performed will also be assessed by the LARCH trial team.

We may also access details and information from health records from national organisations such as NHS digital, cancer registries and admissions, hospital attendance data, GP records or similar records to look at your health status. Data may also be linked with other appropriate research databases where necessary. Limited information such as your date of birth or NHS number, that identifies you, will be sent to these national organisations, to allow the information to be linked together. This will occur periodically and remotely and will not involve any effort on your part. Any researcher who may be accessing your health records will do so in confidence with your consent for this study and will observe best ethical and legal practice.

What safety precautions will be taken to protect me if I choose to take part in this study?

We will try to make sure that you do not have to attend hospital on anymore occasions than you would otherwise have to. We will time all of our research appointments with clinic appointments so no extra visits are required.

Follow up

Any follow-up appointment you have will be as part of your routine care and not as a result of taking part in the study.

What will happen with my information and will it be kept confidential?

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the sponsor for this study and is based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

As we have shown in the table above, we will collect information from you and your medical records for this research study in accordance with our instructions. We will keep your name, NHS number, date of birth and contact details confidential. We will use this information as needed, to contact you about research, and make sure the relevant information about the study is recorded for your care, and to oversee the quality of the study. We will create a unique code assigned to you for this study. Any data we keep about you will be stored securely for 20 years on password protected computers. The only people who will have access to this data will be members of the research team, other researchers who have gained ethical approval to access certain parts of the data and certain individuals from the hospital or the university, or regulatory organisations who may look at your medical and research records to check the accuracy of the research study. Data collected as part of this study will be anonymised, and stored on a secure database. If we share the data with other researchers, it will contain only your unique code with no personal identifiable information included.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep

the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

We will keep identifiable information about you from this study for 20 years, before being securely destroyed.

Invitation for future studies

In the future, there may be further studies conducted on laryngeal cancer, or other conditions, by the study team. We have outlined this in the table above. We may contact you and invite you to take part in these studies that you may be eligible for. You will be provided with full information regarding each study and you are free to decide if you wish to participate or not. Consent to be contacted does not mean you consent to these studies, you will be asked to consent to those specific studies separately. We will closely monitor how frequently this occurs and will restrict the number of times this happens.

What happens with my tissue or biopsy samples?

As is detailed in the table above, any tissue that is taken, from either a biopsy procedure or from a cancer operation, may be stored in a "biobank". It will be handled in confidence and labelled with the unique study ID and contain no identifiable information such as your name or date of birth. The sample may be analysed in future studies, subject to regulatory body and further ethical approval. The biobank may be local to the hospital that you are treated in, or it may be held centrally with all patients from a particular region or country. All material stored will meet the requirements of the Human Tissue Authority (HTA). Some of these tests may be on your genetic make up. You will not receive the results of any of these tests. The Biobanks storing the material for future research may charge researchers for providing them with tissue for their research. This is conducted on a not-for-profit basis, and is in order to cover the costs of storage and keep the Biobank going for future research.

All of your scans will be stored and will be assigned a unique study number. You will not be identifiable from the scans. The scans may be analysed in future studies subject to regulatory body and further ethical approval.

Will anyone else be told about my participation in this study?

We will inform your GP that you are taking part in this study.

Can I withdraw from the study at any time?

You are free to refuse to join the study and may withdraw at any time during the study. This will not affect your care in any way. If you choose to withdraw from this study we will keep and use any data collected about you as part of the study up until that point. This data will be used in the same way as described in the 'What will happen with my information and will it be kept confidential?' section above.

What if something goes wrong?

We believe that this study is safe and we do not expect you to suffer any harm or injury because of your participation in it. The NHS indemnity scheme will compensate you if you are harmed due to someone's negligence but there is no compensation scheme for harm that was not caused by negligence. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during this study, the normal National Health Service complaints mechanisms will be available to you. Information about patient rights, research-related questions and research-related injury can be obtained from the Advice and Complaints Service, Tel **08000320202**

What will happen to the results of the research study?

The results of the research will be published in one or more papers in medical journals so that they are available to all doctors. A summary of the research findings will also be published on the Trust's website for you to view at the end of the study. We aim to develop ways to inform patients who wish to be updated regarding the research. No individual patients will be identified in any publication or report.

Who is organising and funding the research?

The trial has been organised by Mr David Hamilton, Consultant ENT, Head and Neck Surgery at the Freeman Hospital, Newcastle upon Tyne. The Sponsor for the study is The Newcastle upon Tyne Hospitals NHS Foundation Trust. The research study has received its funding from the Medical Research Council (MRC) and National Institute for Health Research (NIHR). They have no influence over or involvement in the research.

Who has reviewed the research?

This study has been reviewed by London - Surrey Borders Research Ethics Committee who have given it a favourable opinion.

What if I have any further questions?

If you have any further questions or you would like to take part in this study please contact the doctor who is conducting the study or their research nurse:

Principal Investigator:

details

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