PARTICIPANT INFORMATION SHEET V5 - 16th October 2017

Can we predict who will get problems in swallowing, mouth opening and damage to the jawbone after radiotherapy?

Introduction

We would like to invite you to take part in a research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish. Part 1 of this leaflet provides a short summary of the study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. If anything is not clear or you would like further information from a member of the research team please call xxxx or email xxxx

Part 1 - Summary of the study

Patients who have had radiotherapy to the head and neck region often have problems with swallowing or mouth opening. These problems may make it difficult to eat certain foods. Some patients are unable to eat enough and have to be fed through a tube. High doses of radiation can also decrease the blood supply to the jawbone. If this happens, the bone gets less oxygen than it needs, which may result in the death of bone tissue. This relatively rare condition is called osteoradionecrosis or ORN. All of these problems can have a negative impact on patients' quality of life.

Research suggests that one or more genes may be linked to the risk of post-radiation complications in the head and neck. We have already studied one gene and found that patients with one variation of the gene had an increased risk of ORN.

In this study we want to test a much larger collection of genes. We want to find out whether we can predict swallowing and mouth opening problems.

DNA is made up of chemical compounds and contains the genetic instructions needed for a plant or animal to develop, survive and reproduce. DNA provides a unique genetic fingerprint for each person. Nearly every cell in a person's body has the same DNA. Genetic tests are done using DNA that has been extracted from a sample of blood or saliva. The tests allow researchers to see which genes are more frequently present amongst those patients with severe complications and/or which genes are present amongst patients with fewer problems. We will compare the genes from all patients.

The study has two phases. In phase you will be asked to fill in a short quality of life questionnaire about your swallowing ability and problems relating to your radiotherapy. In phase 2 you will be invited to attend a research clinic where you will be asked to repeat the quality of life questionnaire. You will also be invited to provide us with a saliva and blood sample for genetic testing, and perform a saliva swallow test.

Part 2 – Further Information

Who is organising the project?
The British Association of Oral and Maxillofacial surgeons and the John Anderson Cancer Research trust have funded the project. Mr Andrew Lyons, an Oral and Maxillofacial Surgeon at Guy's and St Thomas' Hospital NHS Trust, is leading the project and working with the National Facial and Oral Research Centre and your local Head and Neck Team.

What is the purpose of the study?
More than 7,000 patients in England and Wales develop head and neck cancer each year. Many of these patients are treated with radiotherapy or chemoradiotherapy. We want to find out whether genetics can be used to predict who will suffer from severe radiation damage. We hope that in the future patients at high risk could be offered alternative treatments. They could be offered lower does of radiation, radiation that targets only cancer cells or alternative treatments such as surgery.

Currently, we don't know how many patients suffer from complications after having radiotherapy. This study may help us to find this out. It may also tell us about the kind of side effects patients have after radiotherapy.

Why have I been chosen?
We would like all patients who have had radiotherapy or chemo-radiotherapy in the last 1 to 6 years to take part.

Do I have to take part?
No, you are under no obligation to take part. Some people will feel that they do not want to take part. Your care will be exactly the same whether you take part or not.

What do I have to do to take part?
The study has 2 phases.

Phase 1 - is for up to 1,000 patients who have had radiotherapy or chemo-radiotherapy in the last 1-6 years and wish to take part in this study. You will fill in one questionnaire that asks about your swallowing. It will also ask you about tube feeding, mouth opening and ORN. The questionnaire will take about 10 minutes to complete. You will be asked to post it back to the study centre using the Freepost envelope provided.

Phase 2 - is for the same 1,000 patients who took part in phase 1. We will send you a letter inviting you to take part in the genetic testing. This may be several months after you complete your questionnaire, as we need to know everyone's scores. We will ask you to come to a special research clinic.

At the clinic, we will collect a small amount of saliva and about 2 teaspoons of blood. We will also ask you to take part in a short test to assess your swallow ability. For this test, we will wet your mouth with a little cold water. You will then be asked to swallow air, where we will measure the amount of swallows you can make over 30 seconds. We will do this by either watching you or gently feeling your neck area. If you are able, there will also be another swallow test where you will be asked to drink 100ml of water as quickly as possible. The number of swallows and the time taken will be measured. During your visit to the clinic we will also ask you to complete a 2 page questionnaire which asks about how you feel about your own swallowing ability. The questionnaire will only take a few minutes to complete. We will also measure how wide you can open your mouth and assess the level of any tissue damage after your radiotherapy treatment.

The whole process will take about 30 minutes plus some waiting time, which we will try to keep to a minimum. We will reimburse your reasonable travel and childcare costs.

If you are unable or do not wish to attend a research clinic in person, we will give you an opportunity to provide a saliva sample and complete the questionnaire by post.

Are there any benefits in taking part?
This study will not help you directly, but the information we get from this study may help improve the treatment of people with head and neck cancer in the future.

Are there any disadvantages or risks in taking part?
Some patients will need to attend a research clinic to donate blood and saliva. This appointment will be in addition to any other appointments you have. Some patients may experience mild pain or bruising at the blood sample site.

Will my privacy be protected?
When you fill out your questionnaire and agree to donate a sample of blood and saliva, your privacy will be protected in the following ways:

- There will be no identifiable information on the samples such as your name, address, date of birth, which can link back to you.
- The questionnaires and all blood and saliva samples will be labelled with a code that cannot be used to identify you by anyone who is not in the study team.
- Only a few senior members of the study team will be able to look at your personal information such as your name and address and link your samples or questionnaires to you.
- Study documents will be stored in secure locked cabinets within a security-guarded building.
- Information that could be used to identify you e.g. consent forms will be stored separately from the samples and other health related information you provide.
- We will not use any information that could be used to identify you or your family in any report or presentation of the study results.

Can I withdraw from the study once it has started?
You may withdraw from the study at any time. If you have agreed to participate and have completed the questionnaire or provided samples you can still change your mind later. This will not affect your treatment. You just need to let us know. If you wish to withdraw from this study, we may keep some stored samples and data that have already been collected or published as this would be difficult to destroy. However, we can remove all of your personal information and if you prefer, we will not contact you again.

What will happen to any samples I give?
We will label your samples with a study ID that does not include any of your personal details. We will then send your samples to the laboratory for processing. The laboratory will not be able to identify you. Only a few senior members of the study team will know your name and other personal details. Some samples may be frozen and stored in the Bart's Health – Human Tissue Resource Centre (HTRC) before being sent to the laboratory.

Will any genetic tests be done?
Yes. We are trying to find out if genes can predict who is more likely to suffer from impaired swallowing after having radiotherapy. Personal details of genetic testing will not be shared with anyone.

What will happen to the results of the research study?
Anonymised results will be published in international journals and will be presented at conferences. We will also publish the results of the study on Saving Faces – The Facial Surgery Research Foundation's website.

Who is funding the study?
The British Association of Oral and Maxillofacial Surgeons, Saving Faces – The Facial Surgery Research Foundation and John Anderson Cancer Research trust will pay for the study**.**

Who has checked this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Research Ethics Committee South East Coast –Surrey.

Further information and contact details

If you would like specific information on this trial, please contact us on:

Research Staff: Sharon Cheung
Phone Number: 020 8223 8049
E-Mail Address: sharon.cheung@savingfaces.co.uk

Research Manager: Fran Ridout
Phone Number: 020 8223 8049
E-Mail Address: fran.ridout@savingfaces.co.uk

Co-investigator: Dr. xxx (TBC)
Phone Number: (TBC)
E-Mail Address: (TBC)

If you would like independent advice on whether to participate the Patient Advice and Liaison Service (PALS) is a cross-site service offering support, information and help with hospital related queries to patients, their families, carers and friends.

How to contact PALS

The PALS service is available (TBC)

Tel: (TBC)
Email: (TBC)

Thank you for taking the time to read this information sheet

Transparency Information

Queen Mary University of London / Saving Faces is the sponsor for this study 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. Queen Mary University of London Saving Faces will keep identifiable information about you for 20 years after the study has finished.
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.

You can find out more about how we use your information at http://www.jrmo.org.uk/performing-research/conducting-medical-research/setting-up-a-study/#16 under what is GDPR section.

Saving Faces / NHS Trusts will use your name, NHS number, hospital number, date of birth, health information, gender, ethnic origin and contact details such as address and telephone number to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Queen Mary University of London / Saving Faces and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS Trusts will pass these details to Saving Faces along with the information collected from you and your medical records. The only people in Queen Mary University of London / Saving Faces who will have access to information that identifies you will be people who need to contact you to study purposes or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

NHS Trusts will collect information from you and your medical records for this research study in accordance with our instructions. NHS Trusts will keep identifiable information about you from this study for 20 years after the study has finished.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.