TO BE PRINTED ON

HOSPITAL HEADED PAPER

TOxicity Reduction using Proton bEam therapy for Oropharyngeal cancer

Patient Information Sheet

IRAS Project Number: 268843

Sponsor no: CCR5134

Invitation to take part in the TORPEdO study

Radiotherapy can cause side effects. This study aims to find out if a new type of radiotherapy can reduce these side effects and improve quality of life for people who are living with head and neck cancer.

- Before you decide whether to take part, it is important that you understand why this research is being done and what it will involve.
- Please read the information in this sheet carefully. Discuss it with your friends and family if you wish. Take your time to decide.
- Please ask your hospital doctor or nurse/radiographer if there is anything that you do not understand or anything you want to know more about.
- It is your decision whether to take part or not. If you decide not to take part this will not affect the care you receive from your doctors.

Summary

- Radiotherapy is a common treatment for cancers of the tonsil and back of the tongue (an area called the oropharynx). Unfortunately, radiotherapy can be associated with severe side effects, because normal tissues near to the cancer can be damaged by radiotherapy. The side effects can continue in the longer term or develop several years after treatment.
- We want to find out if a new type of radiotherapy called 'proton beam therapy' can reduce these side effects and improve quality of life for patients, when compared with standard radiotherapy, called intensity-modulated radiotherapy (IMRT).
- Approximately 183 people will take part in this study. About two thirds (122) will receive proton beam therapy at one of two NHS proton centres in Manchester or London. The other one third of patients (61) will receive IMRT at their local radiotherapy centre.
- Both types of radiotherapy are given once a day, Monday to Friday, over six and a half weeks.
- If you are treated with proton beam therapy you will visit the NHS proton centre in Manchester or London for one pre-treatment visit (about 3 days). You will then return a week later for the duration of the treatment. This will be about six and a half weeks. If the NHS proton centre is not part of the hospital trust in which you would receive standard radiotherapy (IMRT), you and a family member or carer may be eligible for accommodation near to the centre which will be discussed with you by your key worker. You can also be reimbursed for economy travel costs. You will be able to go home at weekends if you wish.
- You will be supported by a team of doctors, nurses and allied professionals (for example, speech and language therapists and dieticians). This support will be coordinated by your key worker, in discussion with you.
- All patients will be followed up in their local hospital at 6 weeks and 3, 6, 12, 18, 24, 36, 48 and 60 months after treatment. We will ask you to complete several quality of life questionnaires.

How to contact us?

If you have any questions about this research study, please talk to your hospital doctor or nurse/radiographer. You will find their contact details at the end of the information sheet.

Contents

PART 1

1 Why are we doing this study?

We want to find out if a new type of radiotherapy called 'proton beam therapy' reduces long-term side effects and improves patient-reported quality of life, when compared with standard radiotherapy, called intensity-modulated radiotherapy (IMRT).

You have been diagnosed with cancer in your tonsil or back of your tongue (called the oropharynx). The treatment plan for this type of cancer (head and neck cancer) depends on a number of factors such as your general health, the exact location of the disease and how much your cancer has grown and spread.

Radiotherapy and chemotherapy are the main ways of treating this type of cancer. Even when this type of cancer is large or has spread to the lymph nodes in your neck (called locally advanced cancer), it responds well to treatment and there is a good chance of cure. However, the treatment with radiotherapy and chemotherapy can cause severe side effects during treatment and in the long-term, which may have a significant impact on your quality of life. We want to find out if proton beam therapy can reduce these side effects and improve quality of life, when compared with standard radiotherapy, called intensity-modulated radiotherapy (IMRT).There is no suggestion that proton beam therapy would be less effective than IMRT. However, it is uncertain whether proton beam therapy for oropharynx cancer reduces side effects and improves long-term quality of life for patients, which is the reason for doing this study.

2 What is the difference between the two types of treatment in this study?

The standard radiotherapy used to treat your type of cancer is called Intensity Modulated Radiotherapy (IMRT). This uses high energy beams of radiation (X-rays) to destroy cancer cells. It is a targeted treatment, but normal tissues in the head and neck can be damaged by X-rays as they enter and leave the body. This leads to short and long-term side effects. Using proton beam therapy there is less radiation dose deposited to the normal tissues around the tumour. We know from the use of proton beam therapy in other countries (for example, the United States of America) that it is a safe treatment, with similar cancer cure rates compared with standard radiotherapy, and it is thought to cause less damage to healthy tissues. We want to find out whether proton beam therapy reduces long-term side effects and improves patient-reported quality of life, when compared with IMRT.

3 Why am I being invited to take part?

You have been diagnosed with oropharynx cancer. Your hospital doctor has advised you to have radiotherapy (IMRT) as part of your standard treatment. You will also receive a course of chemotherapy during radiotherapy. If you join the study, you will be one of approximately 183 people from across the UK taking part.

4 What will happen to me if I take part?

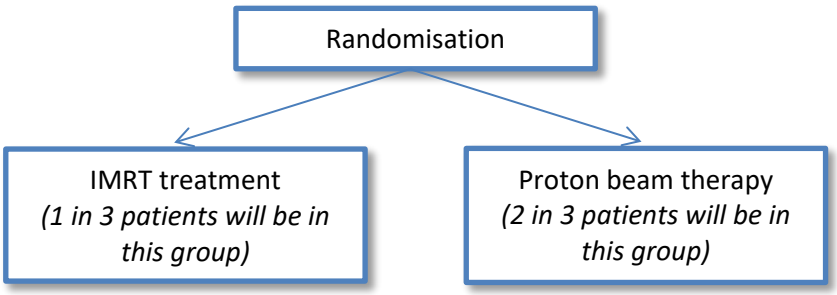
All patients in both treatment groups will need to have a number of routine examinations before you can enter the study. You would have these examinations whether you are on the trial or not, to help determine the extent of the cancer.

These include:

- Blood tests: to ensure your blood count is normal and that there are no problems with your liver or kidneys. A radioactive tracer may be used to measure kidney function. The tracer is injected into your arm and blood samples are taken afterwards to see how well your kidneys are doing at removing it from your bloodstream.
- A physical examination.
- An electrocardiogram (ECG) to assess your heart rhythm.
- A CT scan (computerised tomography). A CT scan is a specialised X-ray test which gives clear pictures of the inside of your body. Some patients may also have a magnetic resonance imaging (MRI) scan which shows the position of your tumour. Sometimes a PET-CT scan is also performed to help see the cancer and make sure it hasn't spread elsewhere.
- Dental assessment before starting radiotherapy which may include dental x-rays. This is to ensure that any existing oral problems are treated before you start radiotherapy.

5 How will you decide which treatment to give me?

If you agree to take part in the study you will need to sign a consent form. Which type of radiotherapy you receive in the study - proton beam therapy or IMRT - is not decided by you, your hospital doctor or any other person. The choice is made at random, by a computer, at the time you enter the study. This process is called 'randomisation'. This is the best way to make sure that the patients in each group are as similar as possible. If one group fares better than another group, it is more likely to be because of the treatment, rather than because the patients in one group are somehow different to those in the other group. If you join this study you will receive either standard IMRT or proton beam therapy.



In TORPEdO for every ONE patient in the IMRT group TWO patients will be randomised to the proton beam therapy. This will help us gather more information about proton treatment and compare this with the standard treatment which is IMRT.

Whichever group you are randomised to, everybody who takes part in the trial will receive the best possible care and regular monitoring by their clinical care team.

Standard IMRT

If you receive standard IMRT you will receive 33 daily doses of radiotherapy to the head and neck, once a day, Monday to Friday, for six and a half weeks. All treatment and follow up will take place at your local hospital.

Proton Beam Therapy

If you receive proton beam therapy you will receive 33 daily doses of radiotherapy to the head and neck, once a day, Monday to Friday, for six and a half weeks. Treatment will take place at either The Christie NHS Foundation Trust in Manchester or University College Hospital in London. You will need to attend for

a pre-treatment visit for radiotherapy planning and treatment. You will then return to your local hospital for the remainder of the study follow up. Part 2 of this information sheet provides more information about the support, accommodation and financial assistance provided to patients receiving proton beam therapy.

6 Planning your radiotherapy treatment

To ensure your treatment is as effective as possible, it has to be carefully planned by your hospital doctor and other specialised staff including radiographers and physicists.

What does the radiotherapy planning involve?

The practical aspects and experience for patients are similar whether you receive proton beam therapy or IMRT. Radiotherapy is a very precise treatment and it is important that you are able to lie still, in the same position for every treatment. To help you lie still and in the same position, a special see through mould called a 'mask' or 'shell' will be made for you. This will help ensure the treatment is delivered accurately. The mask fits over your head, neck and upper shoulders. The radiographer will attach it to the radiotherapy couch each time you have treatment. You will have your mask specially made during your first planning appointment and the appointment usually takes about 30 minutes.

Once your mask is ready, your specialist will plan your radiotherapy treatment very carefully. Treatment planning is a very important part of radiotherapy and more than one visit may be needed.

During your planning visit to the radiotherapy department you will have a CT scan taken of the area to be treated. During the CT scan you will require an injection of an iodine based 'contrast'. If you are receiving proton beam therapy you will also have an image series acquired before the injection of contrast. This will help to highlight the cancer and plan your treatment. You may also need to have an MRI scan as part of the radiotherapy treatment planning process. If you had an MRI scan at diagnosis your hospital doctor will advise you if you need to have another scan.

At the same time the radiographers will take measurements from you that are needed for treatment planning. The session will take about 45 minutes and you will need to wear your radiotherapy mask. All of the planning procedures are part of the routine care for patients receiving radiotherapy to the head and neck area except for the image series acquired before the injection of contrast. For patients who are going to receive proton beam therapy treatment an IMRT contingency plan will be made so that in the event of a machine breakdown so that your treatment can be given on an IMRT machine and there are no delays or gaps in your treatment.

Before treatment, you will also meet other members of the team, for example your key worker, specialist nurse, speech and language therapist and dietician.

7 What other study specific assessments will be performed before I start treatment?

In section 7 and 8, details are given regarding all the assessments during and after treatment. A summary table is given at the end of section 8.

1. A hearing test and jaw motion assessment

As this study involves a comparison of your hearing before and after radiotherapy treatment, we would like you to have a hearing test before treatment, and then at 3, 12 and 24 months after treatment. We also want to see if having either the IMRT or proton therapy treatment affects how far patients can open their jaw and measurements will be taken at the same time as the hearing test.

2. Swallowing function evaluation

As this study involves a comparison of your swallowing before and after radiotherapy treatment we would like you to have several swallowing assessments throughout the study. Your first swallowing assessments will be done before you start any chemotherapy/radiotherapy treatment. These swallowing assessments are called 'baseline' assessments and will consist of the following:

Completion of a questionnaire booklet: there are two questionnaires in the booklet which ask you to give your views about your swallowing. This information will help us to understand how you feel about swallowing. The questionnaires should take less than 10 minutes to complete and will be given to you by a research nurse whilst you are waiting to see your hospital doctor. The research nurse will explain how to fill out the questionnaire and will be available to answer any of your questions but he/she will not direct answers. There are no 'right' or 'wrong' answers.

A water swallowing test: the water swallowing test is a very quick way of assessing your swallowing and may be carried out by a Speech and Language Therapist or a specially trained research nurse. You will be given 100ml of water in a cup and asked to drink it as quickly as you can. The Speech and Language Therapist or research nurse will gently place his/her fingers on your neck so that they can feel you swallowing the water and they will count how many times you swallow. They will also make a note of how many times you need to clear your throat or any coughing during or after the assessment.

3. Completion of a questionnaire booklet

All patients who take part in the study need to complete questionnaires, so we can understand your side effects and how these affected your quality of life. The information will also be helpful to guide your care, as we follow-you up after treatment.

A member of your medical team will explain the questionnaire and answer any questions that you have. Some of the questions may seem to be a bit repetitive but these are standard questionnaires and we would ask you to bear with us and answer them as best you can.

You will be given your first questionnaires in clinic. These will be completed before treatment (to understand your symptoms at the outset), at the end of your treatment, and at 6 weeks and 3, 6, 12, 18, 24, 36, 48 and 60 months after treatment. Each questionnaire booklet should take about 30-40 minutes to complete. From 3 months onwards these will be sent directly to you at your home address from researchers at the Institute of Cancer Research. We need to collect details of your home address in order to do this. We will check with your GP and/or hospital doctor beforehand that you are well. The information you provide in the Quality of Life study will be treated in the strictest confidence.

We would also like to collect information about any hospital visits and hospital activities whilst you are taking part in the trial. In order to do this we will need to use your NHS number to link with national databases. As we are collecting you postcode in order to send you Quality of Life questionnaires we would like to also use this information for further health economic analysis.

8 What happens during my treatment?

Both proton beam therapy and IMRT involve treatment with 33 sessions once daily, Monday to Friday over six and a half weeks.

Each treatment session will take approximately 20-45 minutes, as the radiographer needs to position you on the couch, attach the mask and ensure that you are comfortable before treatment begins. The total amount of time is longer for proton beam therapy than IMRT. This is because IMRT is usually delivered in a continuous circle (or 'arc'), whereas proton beam therapy has up to five separate beam positions. On average, the whole process for each treatment will take approximately 20 minutes for IMRT and 45 minutes for proton beam therapy. You will not feel anything, as it is similar to having an X-ray scan.

You will have a second planning visit in the middle of the third week on treatment where you will receive a repeat CT scan. This will be assessed to ensure that if there have been any changes during the course of treatment your treatment plan is modified to account for them. The dose from the CT scan will be very small compared to radiotherapy and will ensure that the radiotherapy goes to the right place.

How many times will I need to visit the hospital during and after my treatment?

You will be seen regularly by your hospital doctor and/or nurse/radiographer during and after treatment. This is so that he/she can assess the effectiveness and side effects of your treatment.

- During radiotherapy treatment (IMRT or proton beam therapy) you will be assessed every week.
- When the radiotherapy treatment is completed you will receive all further follow-up at your local hospital.
- All patients will be assessed at their local hospital 6 weeks after completion of radiotherapy and then at 3, 6, 12, 18 and 24 months after treatment. After this time we would like to assess you every year for the next 3 years.

You will also have a PET-CT, CT or MRI scan to monitor the effectiveness of your treatment. This will be carried out about 12-14 weeks after the end of your radiotherapy treatment. You may also need to have further PET-CT, CT or MRI scans later during your follow-up.

Summary of assessments.

Those *in italics* are additional assessments because you are taking part in TORPEdO. The rest are considered standard of care.

				After radiotherapy treatment						
ASSESSMENT/VISIT	Pre treatment	Every week during treatment	End of treatment	Week 6	3 months	6 months	12 months	18 months	24 months	Annually at yr. 3,4 & 5
Physical examination (Including height + weight)	X	X	X	X	X	X	X	X	X	
Radiological assessment of disease (MRI /PET-CT/CT thorax)	X				X					
ECG (heart tracing)	X									
Dental assessment	X									
Blood tests (including full blood count, liver function)	X	X	X							
Blood test (kidney function)	X									
Radiotherapy planning visit (for mask fitting and planning CT scan)	X									
Repeat radiotherapy planning CT scan (week 3 of treatment only)#		*X#*								
Hearing test and jaw opening assessment	*X*				*X*		*X*		*X*	
Swallowing function evaluation	*X*				*X*	*X*	*X*	*X*	*X*	
Completion of a questionnaire booklet	*X*		*X*	*X*	*X*	*X*	*X*	*X*	*X*	*X*
Tumour sample donation	*X*									
Blood sample donation	*X*	*X*	*X*	*X*	*X*					

9 Will I be asked to do anything else?

We are asking all patients in the TORPEdO study to take part in some optional research linked to the main study. If you are willing to take part in this additional research we will ask you to consent to the donation of a tissue sample (left over from your biopsy sample when you were diagnosed) and blood sample taken during your follow up at 10 different timepoints. These will be taken alongside your routine hospital bloods to avoid a separate needle stick. You do not have to consent to the donation of these samples. However if you do, it will help us to understand more about head and neck cancer and radiotherapy treatment and may be of benefit to men and women undergoing radiotherapy treatment for head and neck cancer in the future. More details about the donation of these samples can be found in part 2 of this information sheet.

10 What are the possible benefits of taking part in this study?

There is no guarantee that you as an individual will benefit directly from taking part in this study. We hope the information we gain from the study will benefit people who develop head and neck cancer in the future. You will have helped by taking part.

11 What are the possible disadvantages and risks of taking part in this study?

Proton beam therapy is a highly specialised service provided at two NHS proton centres: The Christie NHS Foundation Trust in Manchester and University College Hospital in London. If you receive standard radiotherapy (IMRT) as part of the study, you will be treated by your local hospital trust. If you receive proton beam

therapy (IMPT) and the NHS proton centre is not part of your local hospital trust where you would receive IMRT, you may need to be away from home during treatment. If this is the case, you and a family member or carer may be provided with accommodation near to the proton centre. You will also be supported by a team of doctors, nurses and other health professionals at the proton beam centre. The eligibility for accommodation will be explained by your key worker (a specialist nurse or radiographer from one of the proton centres) and has to be approved by the NHS. If you are staying in accommodation you can be reimbursed for economy travel costs to the accommodation from your home, including screening and treatment. The need to travel and stay away from home is something to be considered carefully before agreeing to take part in the study. Further information will be provided separately, should this be applicable to you.

Proton beam therapy is a standard treatment in the UK for some other head and neck cancers (for example skull base cancers) and in other countries (for example, United State of America) for treatment of oropharynx cancers. It is routinely used in children or young adults (less than 24 years old) who require radiotherapy. There is no suggestion that proton beam therapy would be less effective than IMRT. However, it is uncertain whether proton beam therapy for oropharynx cancer reduces side effects and improves long-term quality of life for patients, which is the reason for doing this study.

Pregnancy during treatment

Chemotherapy and radiotherapy can be harmful to a developing baby. You should not become pregnant before, during or for six months after treatment. Appropriate contraception should be used. Your clinical team can advise you on appropriate methods of contraception. If you think you may be pregnant, you must tell the chemotherapy nurses, radiographers or your hospital doctor before you have any treatment.

Side Effects of Radiotherapy or Proton Beam Therapy Treatments in this Study

If you are in the group of patients receiving IMRT there is the possibility that you may experience more side effects than patients receiving proton beam therapy. However, we do not know whether this will be the case and one of the aims of this study to investigate this further.

Radiotherapy side effects usually build up gradually during your treatment. Most people experience some side effects. They are usually at their worst by week 5 to 6 of your treatment and continue at their peak for 2 weeks after completion of their treatment. Then over the next 4 weeks or so your treatment side effects will slowly start to get better. All types of radiotherapy including IMRT to the neck area may cause:

- Tiredness or fatigue
- Sore red skin to the area being treated (like a sunburn reaction)
- Weight loss
- A sore throat and mouth (your throat may become more sore as you go through treatment)
- Pain on swallowing
- Difficulty swallowing
- A dry mouth
- Loss/change in taste
- A hoarse voice

No-one can predict whether you will have some, all or none of these side effects, or how severe they will be. It is important that you tell your hospital doctor or study nurses about any problems you have at each hospital visit. You can telephone your nurse or hospital doctor between visits if you are concerned. The numbers are at the end of this information sheet.

Are there any other long term risks of radiotherapy or proton beam therapy?

Ionising radiation can cause cancer (in around 1 in 100 people who have had radiotherapy) which can appear after many years or decades after treatment. The risk of developing cancer as a result of radiotherapy is an accepted side-effect and should be balanced with the risk of not having radiotherapy. It is possible that proton beam therapy reduces the risk of secondary cancers in the long-term.

Are there any radiation risks associated with CT scans, X-rays or radioactive tracers?

When you have a CT scan, an X-ray or have a radioactive tracer administered (for kidney function tests and PET scans) you will be exposed to low levels of ionising radiation. You would have most of these tests / scans if you did not take part in the study. The radiation dose from these tests / scans will be very small compared to the dose from your radiotherapy and will not significantly change the risk of developing cancer at a much later date.

12 What if tests show I am not suitable for this study? What are the alternatives for treatment?

If for some reason the tests show you should not take part in the study your hospital doctor will discuss alternatives with you.

13 What happens if I don't want to carry on with the study?

You are free to withdraw from the study at any time. You do not have to give a reason and your future treatment will not be affected. Your doctor will discuss your treatment with you and will offer you the most suitable treatment available.

However, if you were to withdraw, we would like your permission to keep the information and samples we have already collected from you and to continue to collect information on your progress that is routinely recorded in your medical records.

This completes PART 1 of the Information Sheet

If the information given in Part 1 of this information sheet has interested you and you are considering participation in the TORPEdO study, please read the additional information in Part 2 before making a decision.

PART 2: More information you need to know if you take part.

1 Support for patients receiving proton beam therapy.

If you are allocated to proton beam therapy you will need to visit one of the two national NHS proton centres for treatment planning and the treatment itself. The proton centres are located at the Christie NHS Foundation Trust in Manchester and the University College Hospital London. Following your confirmation that you wish to take part in the study you will be contacted by a key worker (a named specialist nurse or radiographer from one of the proton centres), who will provide assistance and support throughout your treatment. If the proton centre is not part of your local hospital trust where you would receive standard radiotherapy (IMRT), you and a family member or carer may be provided with accommodation near to the proton centre. Your key worker at the proton centre will call you to discuss travel and accommodation during treatment and to answer any questions you have before you arrive at the hospital. Please read all information you have received from your local hospital before this phone call, so that they can best manage your questions.

Accommodation during Proton Beam Therapy

If the NHS proton centre is not part of the hospital trust in which you would receive standard radiotherapy (IMRT), accommodation arrangements will be made by the key worker from the proton centre. This would be for you plus one family member or carer for your planning visit and for the whole of your six and a half weeks of treatment. The types of accommodation available will vary to accommodate your specific needs. You do not have to stay in the provided accommodation if you live close to the NHS proton centre and would prefer to return home every day following your treatment

Only accommodation approved by the NHS proton centre will be funded by the NHS. Further details about the accommodation provided will be provided by your local hospital.

Is there any financial support available?

If you are staying in accommodation provided by the NHS proton centre, economy travel for you and your family member or carer can be reimbursed for a maximum of 4 return trips (each) from your home to the provided accommodation near to the proton centre. This is intended to cover the costs of your travel during screening and treatment. Once you have received your visit schedule from the key worker at the proton centre you will need to make your own travel arrangements. Your expenses will reimbursed by the Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) from a grant from Cancer Research UK and the Taylor Family Foundation. Your key worker will provide you with a document which explains how to claim these expenses. Any claimed travel costs for patients and family members or carers are subject to specific conditions outlined in the '*Guidance on the Reimbursement of Travel Expenses'* for the TORPEdO study, which will be available from your key worker at the proton centre or the research nurse at your local hospital. Travel expenses are only available for patients who are staying in the accommodation approved by the NHS proton centre.

2 What happens when the TORPEdO study treatments stop?

It is known that a small proportion of patients may still have persistent disease after completing radiotherapy. All patients are assessed carefully for this after the early side effects have settled. If there is any suspicion of any persistent disease in the throat or the lymph glands your hospital doctor will advise you if you need to see a surgeon to have an operation to remove this persistent disease.

3 More information about the optional studies

Donation of a Tissue Sample

When you were diagnosed a small sample of your throat cancer was removed and some further tests were done to help decide on the best treatment for you. Any of the cancer tissue left over is then stored in your hospital's pathology laboratory. We would like you to donate some of this stored tissue for future research into throat cancer. You will not have to do anything for this part of the study.

Donation of Blood Samples

We will ask you to donate a blood samples at the following timepoints (20 ml is approximately 4 teaspoons of blood):

Type of blood sample	Before treatment visit 1	Before treatment visit 2	End of week 1 of RT	End of week 2 of RT	End of week 3 of RT	End of week 4 of RT	End of week 5 of RT	End of week 6 of RT	End of week 7 of RT	6 weeks after finishing RT	3 months after finishing RT
EDTA blood (10 ml)	X										
Streck bloods (40ml pre-treatment; 30ml thereafter)		X				X				X	X
EDTA blood (30 ml)	X				X			X		X	
EDTA blood (10 ml)	X	X	X	X	X	X	X	X	X		X

What will happen to any samples I give?

Samples collected as part of the TORPEdO study will be sent to a specialist research laboratory in Manchester where they will be stored securely in accordance with national guidelines. All samples you donate will be labelled with your study number, initials and date of birth only to maintain your confidentiality.

The samples you donate may be used for research associated with TORPEdO but also in the future for analysis that could include genetic analysis. It is possible that the future research will be carried out outside of the UK but within the European Union. The results will be used to try to discover why some patients have a more severe reaction to radiotherapy treatment than others. It will not be possible to release the results of these blood tests to you or your hospital doctor and they will not form part of your medical records. Please initial the consent form if you are happy for this analysis.

We may in the future share the information we gain from the samples you provide with other researchers investigating this type of cancer. You will not be identifiable from this information. Please initial the consent form if you are happy for this information to be shared.

After the TORPEdO study is complete, we would like to store your samples for use in future studies. Any research using your samples will have approval from a Research Ethics Committee. Please initial the

consent form if you are happy for you initial the consent form if you are have for your samples to be stored for future analysis.

4 Confidentiality

Who will have access to my data?

The Institute of Cancer Research 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. The Institute of Cancer Research will keep identifiable information about you for at least 5 years after the study has finished.

The Institute of Cancer Research's lawful basis for processing your information is for the performance of a task carried out in the public interest and it is necessary to process sensitive health and genetic information for the purposes of scientific research with appropriate safeguards in place to protect personal information, as required by the General Data Protection Regulation (GDPR).

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 www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency.

[Insert appropriate name for NHS site] will collect information from you and/or your medical records for this research study in accordance with our instructions.

[Insert appropriate name for NHS site] will use your full name, hospital number, date of birth, postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland) 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.

Will my taking part in this study be kept confidential?

All information which is collected about you during the study will be kept strictly confidential. When you join the trial, your full name, hospital number, date of birth, postcode and NHS/CHI number will be passed to The Institute of Cancer Research Clinical Trials and Statistics Unit (ICRCTSU) where the study is being coordinated. You will be given a unique trial ID number, which will be used together with your initials and date of birth on forms that the research staff at your hospital will send to ICR-CTSU. All information about you will be stored securely. It will be treated as strictly confidential and nothing that might identify you will be revealed to any third party. Only members of the research teams at your hospital and the ICR-CTSU will have access to the information that could allow this trial ID number to be linked to you.

From time to time we would like to know how you are getting on. Ideally we would like to do this for life, and we would like to use national records, which are kept on everyone's health status to find this out. One of these is held at the General Register Office (GRO). We will need to give them enough information to identify you. This is usually your name, date of birth, postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland). Any details we receive from any source are confidential

and will only be used for the purposes of the trial. Please initial the consent form to show that we have your permission to do this.

Representatives from the ICR-CTSU, the NHS Trust relevant to your taking part in research and ethics committee approving the trial and third parties (which may have offices outside of the UK/European Economic Area) approved by ICR-CTSU may need to see your hospital or clinic records to the extent permitted by applicable laws and regulations to make sure the information received is correct. All information will be kept confidential.

[Insert appropriate name for NHS site] will keep identifiable information about you from this study for at least 5 years after the study has finished.

If you decide to take part in this study your General Practitioner (GP) will be informed.

Radiotherapy imaging

As you will be receiving radiotherapy in this study a copy of the imaging (such as CT and MRI) used to design your treatment plan will be sent to the Radiotherapy Quality Assurance team and researchers at the University of Manchester/Christie NHS Foundation Trust. The data is sent electronically by an NHS secure file transfer system and your name will not be included in any of the files sent. We need to send this information to the Quality Assurance team to make sure that radiotherapy given to patients is consistent across the different hospitals taking part. In addition, researchers at the University of Manchester/Christie NHS Foundation Trust are analysing all the radiotherapy imaging collected in this trial to see whether they can predict which patients would benefit from proton beam therapy. The organisers of this study may use the information and images (including any future imaging) for future research into radiotherapy treatment, but the information stored for future research will not contain your name.

Will information about me be shared with other researchers? When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations now or in the future. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

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.

Our main privacy policy can be found at https://www.icr.ac.uk/legal/privacy. If you have any questions about your rights under the GDPR or how we use your information please contact our Data Protection Officer at dataprotectionofficer@icr.ac.uk.

5 Further information

What if something goes wrong?

It is unlikely that anything will go wrong with your treatment or care, but if you wish to complain about any aspect of the way you have been treated during the course of the study you can do so using the normal NHS complaints procedure.

Healthcare professionals working on Clinical Trials are covered by NHS Indemnity and if you are harmed by taking part in this study you may have grounds for a legal action but you may have to pay for it. The Sponsor of this trial holds a clinical trials insurance policy.

If you do wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you. Concerns should be raised by speaking to a member of staff at your hospital or by talking to the local Patient Advice and Liaison Service (PALS) which has been established in every NHS Trust and Primary Care Trust (PCT).

What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, your hospital doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your hospital doctor will make arrangements for your care to continue.

Who is organising and funding the research?

TORPEdO is organised by leading cancer specialists at The Christie NHS Foundation Trust in Manchester together with the Institute of Cancer Research in Sutton, Surrey. It is being coordinated by The Institute of Cancer Research Clinical Trials & Statistics Unit and has been funded by Cancer Research UK. The funding helps to cover the cost of including you in the study and helps support the study staff. None of the researchers are personally benefiting from this grant.

How have patients and the public been involved in this study?

In designing this study we have taken into account the opinions of former patients (patient advocates) on the frequency of participant visits and the support needed for patients attending the proton centres. These patient advocates have also been involved in reviewing this patient information sheet.

Who has reviewed the study?

Cancer Research UK has reviewed the TORPEdO study and supports the aims of the study. TORPEdO has also been approved by the North West - Greater Manchester West Research Ethics Committee, the Sponsor Committee for Clinical Research (CCR) and Health Research Authority (HRA). Their approval means they are satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given the right information to decide whether to take part.

What will happen to the results of the study?

Independent experts will review the progress of the research and the results will be published in a medical or scientific journal as soon as there is enough information to be sure the results are reliable. It is not expected that the results of the trial will be available before 2025. You will not be identified in any report or publication. The results will help to decide how to treat throat cancer in the future.

What happens now?

Your hospital doctor or research nurse/radiographer will be happy to answer any questions. Once you have reached your decision please let your hospital doctor or research nurse know. If you choose to join the TORPEdO study you will be asked to sign a consent form and will be given a copy to keep together with this information sheet.

6 Contacts

CancerBACKUP is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. You can contact one of their specialist cancer nurses on their freephone number, 0800 800 1234. You can also look on their Internet website, to do this go to www.cancerbackup.org.uk.

You can learn more about clinical trials on the Cancer Research UK's patient website (www.cancerhelp.org.uk).

Macmillan Cancer Support is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. You can contact one of their Cancer Information nurse specialists on the Macmillan Support Line: Freephone 0808 808 00 00 Monday to Friday, 9.00am to 8.00pm. In addition to their nurses, the Macmillan Support Line also has other specialist teams that can provide advice and information relating to welfare benefits, financial issues and everyday practical concerns. You can also learn more about clinical trials on the Cancer Research UK's patient website http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial.

If, at any time, you have any questions about the study you should contact your hospital team:

Local Consultant: Name, Address, Telephone, E-mail [details to add]

Local Nurse/Radiographer: Name, Address, Telephone, E-mail [details to add]

Key Worker from the proton centre (if applicable): Name, Address, Telephone, E-mail [details to add]

24 Hour Contact Number, 7 days a week: [details to add]

Local PALS contact details: [details to add]

Thank you for interest in our research.

7 Glossary

Abbreviation	Full Name	What it means
CT scan	Computerised Tomography scan	A CT scan uses x-rays to take detailed pictures of inside your body from different angles. A computer then puts them together to give a series of pictures.
ICR-CTSU	The Institute of Cancer Research Clinical Trials and Statistics Unit	The organisation carrying out the day to day work on the trial.
IMRT	Intensity-Modulated Radiotherapy	IMRT is a type of conformal radiotherapy. Conformal radiotherapy shapes the radiation beams to closely fit the area of cancer.
MRI scan	Magnetic Resonance Imaging scan	An MRI scan creates pictures using magnetism and radio waves. It produces pictures from angles all around the body and shows up soft tissues very clearly.
PET scan	Positron Emission Tomography scan	This type of scan can show how body tissues are working, as well as what they look like.
Proton Beam Therapy	-	Proton beam therapy is a type of radiotherapy that uses a beam of high energy protons, which are small parts of atoms, rather than high energy x-rays (called "photons") which standard radiotherapy uses, to treat specific types of cancer. Proton beam therapy enables a dose of high energy protons to be precisely targeted at a tumour, reducing the damage to surrounding healthy tissues and vital organs which is an advantage in certain groups of patients or where the cancer is close to a critical part of the body such as the spinal cord.