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PATIENT INFORMATION SHEET (Main Study)

Part 1

PROTIEUS

A Randomised Phase 2 Trial Comparing Proton versus Photon Based Neoadjuvant Chemoradiation, followed by standard therapy, in Oesophageal Cancer

IRAS No.: 329646

Introduction:

University College London (UCL) are inviting you to take part in a research study called **PROTIEUS**.

Before you decide whether you should take part in this research study, we would like you to understand why the research is being done, what it will involve and what the possible risks and benefits may be. Your hospital doctor will go through this Patient Information Sheet with you and answer any questions you may have.

Please take your time to read the information carefully and talk to others about this study if you wish. If you choose not to take part, this will not affect the care you receive in any way. You can also decide to stop at any time without giving a reason.

If you decide to take part, your hospital doctor will ask you to sign a form to give your consent to take part in the study.

In this study we will use information from you and your medical records. We will only use information that we need for the research study. We will not be collecting your name or contact details for this study; however, your hospital doctor and study team will have access to this information to help with our study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

Part 1 of this Patient Information Sheet provides you with a summary, and if you would like to find out more, **Part 2** goes on to tell you about the aims of the study and what will happen if you take part and gives you more detailed information about how the study will be run.

Your hospital doctor or member of the study team will be available if you have any questions at all, and their contact details are found in the next section of this Patient Information Sheet.

Patient Video:

To find out more about the PROTIEUS trial you can watch the PROTIEUS patient video online:

www.ctc.ucl.ac.uk/QR/protieus-1.html

Important things that you need to know:

Who is it for?

- You have been invited to take part in this research study because you have been diagnosed with oesophageal (food pipe) cancer.
- Your hospital doctor is considering using chemotherapy and radiotherapy at the same time before surgery as your treatment, and immunotherapy or chemotherapy before and after surgery if suitable.
- Although effective, chemotherapy and radiotherapy treatment can cause side effects and may lead to severe complications after your surgery.

What is involved?

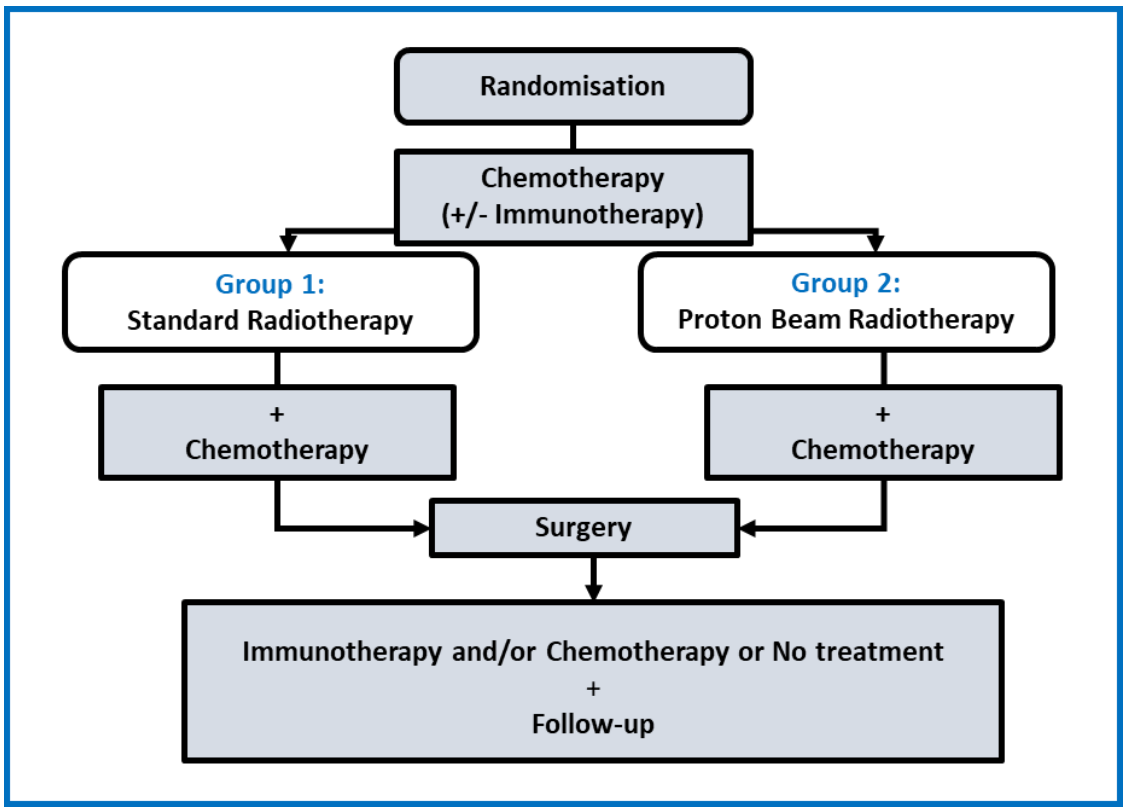
- If you decide to take part in this study, you will be randomly allocated ('randomised') to one of two groups. Depending on which group you are randomly assigned to, you will either receive:

    - **Group 1: Standard treatment arm:** Chemotherapy, standard radiotherapy, surgery and immunotherapy.

    - **Group 2: Investigational treatment arm**: Chemotherapy, Proton Beam Therapy (a new type of radiotherapy), surgery and immunotherapy.

- Both types of radiotherapy are given once a day, Monday to Friday for 3 weeks (15 sessions of radiotherapy in total).
    - Standard radiotherapy will be given at your local hospital
    - Proton Beam Therapy will be given at 1 of 2 Centres (in Manchester or London)
- Systemic anti-cancer treatment (SACT) is a term used to describe all types of drugs used to treat cancer, and patients with your type of cancer might receive standard SACT of chemotherapy and immunotherapy before and after surgery.
- Chemotherapy will be given weekly for 2 weeks, or fortnightly for 8 weeks before radiotherapy according to your hospital's usual practice.
- You may also be given a type of drug treatment called immunotherapy with chemotherapy if your hospital doctor thinks that you are suitable.
- There will be 3 cycles of weekly chemotherapy given alongside radiotherapy. Chemotherapy and immunotherapy are given as an intravenous drip (into your veins).
- You will be seen again in your local hospital with a repeat scan within 4-6 weeks of finishing radiotherapy, and if suitable, you will go on to have routine surgery at your local centre within 4-8 weeks of completing chemotherapy and radiotherapy.
- Within 4-12 weeks after surgery, you may be given immunotherapy which will be given as an intravenous drip (into your veins) every 2-6 weeks for up to one year to reduce the chances of your cancer returning.
- Immunotherapy is a type of drug treatment that uses your body's own immune system to treat your cancer. It has been shown to be safe and effective in many cancers including oesophageal cancer.
- Your doctor may choose to give you chemotherapy and/or immunotherapy after surgery. This is standard treatment.
- You will be seen again at your local centre at 1, 3, 6, 9 and 12 months after your surgery. We will ask you to complete several quality-of-life questionnaires.

The flowchart below summarises your treatment if you take part in the PROTIEUS study.



Aims:

- The main aim of this study is to find out if proton beam therapy can reduce the number of severe complications after surgery compared to standard radiotherapy.

More about proton beam therapy

If you are allocated group 2 (proton beam therapy) you will visit the NHS proton centre in either Manchester or London for a visit for 1-2 days for your treatment to be planned. You will then return to the NHS proton centre in Manchester or London 2-3 weeks later where you will stay for the duration of your radiotherapy treatment (approximately 3 weeks). If you do not live near the NHS proton centre, free accommodation near to the centre will be arranged for you (and a companion) by your proton beam therapy team. You will be able to go home at weekends if you wish.

You will be supported by a team of doctors, nurses, and other professionals (for example, dieticians and physiotherapists who will help prepare you for treatment by improving fitness and wellbeing). This support will be coordinated by your key worker and team, in discussion with you.

We hope the information we receive from you taking part in this study will benefit the treatment of patients in the future.

If you have questions

We hope you find **part 1** of the information sheet helpful. If you are interested in taking part in this trial, we will provide you with **part 2** of the patient information sheet and will be happy to discuss the study as often as you wish to explain what is involved, and clarify things so that you understand. We appreciate it may not answer all your questions, so please use the question/comments section below and do not hesitate to contact us on the telephone numbers below if you would like to discuss any aspect of the study further. Feel free to discuss it with your family, friends, and your GP. In addition to this information with regards to the study, you will also be given extra detailed information leaflets on chemotherapy, radiotherapy, surgery, and immunotherapy. Information about how health researchers use information from patients is also available from the Cancer Research UK & University College London Clinical Trials Centre website: https://www.ctc.ucl.ac.uk/Privacy.aspx

Local Hospital Contacts:

If you have any questions, please do not hesitate to discuss them with your hospital/study doctor or members of the study team:

Your hospital/study doctor is:

Name:

Contact phone number:

Your study specialist nurse/study coordinator is:

Name:

Contact phone number:

Thank You:

Thank you so much for considering taking part in this study and for taking the time to read **Part 1** of this Patient Information Sheet, which is yours to keep. If you would like more information about taking part in the study we will also give you **Part 2** of this Patient Information Sheet which goes into more detail.

Questions/Comments:

The space below is for you to write down any questions you would like to ask your hospital doctor or research nurse about taking part in the study.