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ELIPSE

The ELIPSE Study – a study of lymph node removal in patients having prostatectomy

Participant Information Leaflet

We would like to invite you to take part in the ELIPSE study: a research study looking to understand which of the two types of surgery for prostate cancer is better:

- Removal of the prostate and some of the surrounding lymph nodes, OR
- Removal of the prostate alone.

Both types of surgery are routinely used in the NHS but it is not known if one is more effective than the other.

We are sending you this information because your clinical team feel you are ideally suited for this study. If you were to take part, following a detailed consultation , you will be allocated to one of the two types of surgery. After surgery, you will receive follow-up as part of standard NHS care. We will ask you to complete five questionnaires over three years and we will collect important clinical information from your medical records. For more information about what taking part would involve, see section 1.3 of this leaflet.

By taking part in the study, you will be helping future patients. Their families and their healthcare teams make decisions based on high quality evidence generated from this study (please see section 1.4 for more information).

There is no obligation for you to take part (please see section 1.6 for further information.

You can find contact details for the ELIPSE study team at the end of this leaflet.

Contents of this leaflet

Part 1 – the purpose of the study and what will happen if you take part

1.1 What is the purpose of this research study?

Around 50,000 people are diagnosed with prostate cancer each year in the UK. Prostate cancer that has not spread elsewhere in the body, but is at risk of doing so, is called high-risk localised prostate cancer.

Between 30-50% of men with high-risk localised prostate cancer can get a recurrence of cancer **after surgery**. Surgery involves either removal of the prostate or in some cases removal of the prostate and some of the nearby lymph nodes (which are part of the body's immune system). Both these operations are routinely carried out in the NHS. However, there is no definitive evidence whether removing lymph nodes reduces the chance of cancer recurrence.

The purpose of this study is to answer the question, *'Is removing these lymph nodes better than not removing them?*' The way we find this out is by doing a randomised clinical trial.

The ELIPSE study will compare these two types of surgery:

- removal of the prostate with removal of some of the surrounding lymph nodes
- removal of the prostate alone

To compare these two types of surgery, we will need to collect information on a number of things, including any details of surgery and complications, quality of life and the results of any medical tests after surgery.

The study will run for 6 years in total (each man who takes part will be in the study for 3 years) and aims to involve 1080 men from hospitals across the UK.

1.2 Why have I been approached?

Your surgeon and team have carefully considered your case, feel you are eligible and would like to offer you the opportunity to take part.

1.3 What would taking part involve?

If you decide to take part, you will be randomly allocated (randomised) to one of the two types of surgery. Being randomised means that neither you nor your surgeon (or healthcare team) will decide which type of surgery you receive, but we will tell you whether you are allocated to:

- Removal of the prostate and some of the surrounding lymph nodes, OR
- Removal of the prostate alone.

There is an equal chance that you will be allocated into either group. This helps make sure that the research study compares groups of similar individuals where the only

difference is the type of surgery. This is the best scientific way to answer a question and is referred to as a randomised clinical trial.

If you decide to take part, we will ask you to complete a consent form confirming that you are happy to take part and a questionnaire (which should take about 15 minutes) about your quality of life and your recent contact with the NHS. Both of these can be completed during a routine hospital visit or at home to suit you.

Your surgical team will arrange a date for your surgery. If you have some lymph nodes removed during the surgery, the surgeons will record a surgical image (like a photograph) showing this. It would not be possible to identify you from the image. The image will be used for quality control in the study and will be part of the study data that we collect. A panel of surgeons who are helping with the ELIPSE study will look at the image to confirm that the lymph nodes have been removed.

After your surgery, we will collect some information from your medical records. You will receive all the usual care within the NHS during and after your surgery. This will usually involve regular PSA (prostate specific antigen) blood tests. If you need any additional tests or treatment, your hospital or your GP will arrange this for you. We will

ask you to complete questionnaires while you are taking part in the study. These are described in the table below. Some of these are of a personal nature (for example about continence and sexual function). If there are questions you do not want to answer, you can leave them blank. Each of these will take about 15 minutes to complete.

	What the questionnaire asks about
When you join the study	Quality of life, recent contact with the NHS
3 months after surgery	Quality of life, time to return to normal activities, any complications you have had
1 year after surgery	Quality of life, use of healthcare services, including how much time it takes you to get to appointments and what it costs you, any further treatment for prostate cancer, whether your health impacts work or regular daily activities, any out of pocket expenses, any complications you have had
2 years after surgery	Quality of life, use of healthcare services, any further treatment for prostate cancer, whether your health impacts on work or regular daily activities, any out of pocket

	expenses, any complications you have had
3 years after surgery	Quality of life, use of healthcare services, any further treatment for prostate cancer, whether your health impacts on work or regular daily activities, any out of pocket expenses, any complications you have had

We can send each of these questionnaires to you by post (along with a pre-paid return envelope), or by email or text message (with a link to complete them online) depending on your preference. We may send you reminders about completing them to make sure relevant information about you is recorded for the study. When we send you the 3 year questionnaire, we would like to send you a £15 voucher as a token of our appreciation. If you do not wish to receive this, we will donate it to the Prostate Cancer UK charity.

Finally, at 36 months you will receive a telephone call from your local team where they will ask you if you had any additional visits to hospitals other than the one where you had surgery.

After your surgery, as part of standard NHS care, you will

have regular PSA blood tests and any additional tests or treatment as deemed necessary by your local team. We will collect information about these from your medical records.

We hope to be able to follow ELIPSE participants up for longer than 3 years by using routinely collected NHS cancer registry data We do not have the funding for this longer term follow-up yet, but we will ask for your permission when you join the study. You can take part in ELIPSE without agreeing to this long-term follow-up.

1.4 What are the possible benefits of taking part?

You may not benefit personally from taking part in the study. However, by taking part, you will be directly helping us to understand the best treatment for men who need to have prostate cancer surgery in future.

1.5 What are the possible disadvantages, risks and side effects when taking part?

We do not think that there are any study specific disadvantages to you as both types of surgery are safe, well established and already routinely used in the NHS to treat patients with prostate cancer.

There are risks of complications with any surgical procedure. Steps are always taken to minimise these risks.

The complications that can occur after surgery include injury to nerves and blood vessels, fluid collection at the operating site and blood clots. Sometimes these complications cause pain, infection, swelling of the scrotum or legs, problems passing urine, and blood clots in the legs or lungs.

Previous studies have suggested that there may be a slightly higher chance of complications following surgery where lymph nodes are removed but that removing lymph nodes might reduce the chance of cancer recurrence. However, these studies do not provide the conclusive evidence that men need in order to make a balanced decision. This is the reason why we are doing the ELIPSE study.

Whichever treatment group you are allocated to, your surgery will be performed by a competent and trained surgeon. As part of your routine care, your surgeon will tell you about the risks and benefits of each type of surgery.

If you take part in the ELIPSE study, we do not anticipate any **additional** risk to you over and above the risk of surgery itself.

1.6 Do I have to take part?

No. It is entirely up to you whether you take part. Please take as much time as you need to make this decision. You can read this information leaflet as many times as you wish and ask your surgeon and/or research nurse as many questions as you like.

If you decide not to take part, your surgeon will discuss with you which type of surgery you will have.

If you do decide to take part, you can decide at any time to withdraw from the study. This decision will not affect the standard of care you are receiving now or in the future. If you make this decision, you should continue attending appointments with your consultant and/or GP as part of your routine care.

Part 2 - more information about how the study is run

2.1 What happens when the research study stops?

When the study finishes, you will continue to receive all the normal care from the NHS. If the study is stopped earlier than expected for any reason, we will tell you and arrange continuing care for you.

2.2 What if relevant new information becomes available?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, the ELIPSE team will contact you to let you know about the choices available to you. However, we are not aware that any new information is likely to become available before the end of this study.

2.3 What if there is a problem?

If you have a question or concern about the study, you can ask to speak with the research team who will do their best to answer your questions. Contact details for your local study nurse and the Study Office can be found on the end of this information leaflet.

If you wish to complain formally or have any concerns about any aspects of the way you have been approached or treated during this study, you can do this through the normal NHS Complaints Procedure. You can find information about who to contact at the end of this leaflet.

We do not expect any harm to come to you by taking part in this study.

However, if you believe that you are harmed by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsor of this study, the Cardiff and Vale University Health Board.

As a patient of the NHS, if you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs (as you would in standard NHS care).

The normal National Health Service complaints mechanisms will still be available to you.

2.4 Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information which is collected about you for the purpose of this research study will be handled in strict confidence and

securely stored by the University of Aberdeen who are managing the study on behalf of Cardiff and Vale University Health Board.

2.5 How will we use information about you?

We will need to use information from you and your medical records for this research project. This information will include your name, contact details, date of birth and NHS number. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

2.6 What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study we will keep, and continue to use, all your previously collected data. We would like to continue collecting information about your

health from your medical records. If you do not want this to happen, tell us and we will stop. This information will remain confidential and will not be used for any other purpose. To safeguard your rights, we will use the minimum personally-identifiable information possible.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

2.7 Who will have access to my information if I take part in the study?

The local research team at the hospital that you were recruited in will have access to your information. They will use your name and contact details to contact you about the study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. They may contact your GP to request routine blood tests to check your PSA levels and to collect relevant information from your medical records.

The study team, who are managing the study, are based in the Centre for Healthcare Randomised Trials (CHaRT) at the University of Aberdeen. They will have access to your information to contact you about the study, for example to send you the questionnaires, and for quality control purposes, such as checking the data collection process. All

electronic data collected for the purpose of the research study will be confidentially and securely stored on computer servers maintained by the University of Aberdeen. The local research team will pass information collected from you and your medical records to the study team.

We will tell your GP you are taking part.

The statistical and health economic analysis of this study is being conducted at the University of Aberdeen. To maintain confidentiality, these teams will only analyse completely anonymous data. (Anonymous data does not include names or addresses, and it is not possible to identify individual participants from anonymous data).

Other individuals from the Cardiff and Vale University Health Board (who sponsor the study), and the Research and Development Department of your local NHS Organisation may look at your medical records and data collected for the study, to check that the study is being carried out correctly and to check the accuracy of the research study. All will have a duty of confidentiality to you as a research participant.

Other researchers may wish to access anonymous data from this study for future research. If this is the case, they would be expected to follow legal, data protection and

ethical guidelines. It will not be possible to identify you from this data. The information will only be used for the purpose of health and care research and cannot be used to contact you or affect your care.

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.

2.8 How long will my information be kept?

All information which is collected about you during the research, including identifiable data, will be held securely for 5 years after the study has finished in accordance with Sponsor requirements and data legislation.

2.9 Who is responsible for my information?

The Cardiff and Vale University Health Board and University of Aberdeen are joint data controllers for this study and are responsible for looking after your information, using it properly and complying with your rights.

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- on our website https://cavuhb.nhs.wales/use-of-site/privacy-policy/ and in our leaflet available at https://cavuhb.nhs.wales/files/privacy-policy/patient-privacy-notice-1-1-pdf/

- by asking one of the research team
- by sending an email to the Sponsor Data Protection Officer at cav.ig.dept@wales.nhs.uk
- by ringing the Cardiff and Vale University Health Board Data Protection Officer on 029 2074 4870

2.10 What will happen to the results of the study?

We will use the results of the study to make recommendations on the best type of surgery for men with a high-risk localised prostate cancer. We will publish the results of this study in scientific journals and present the information at appropriate meetings. You will not be identified in any publication resulting from the study.

We will write to you to let you know the results of the study when it is finished unless you tell us that you do not wish to know.

2.11 Who is organising and funding the study?

This study is sponsored by Cardiff and Vale University Health Board who have overall responsibility for the management of the study. The study is funded by the National Institute of Health and Care Research (NIHR, the research arm of the NHS). The research is being carried out by a group of experienced prostate doctors and surgeons from across the UK, in collaboration with

researchers from the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen.

2.12 Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given a favourable opinion by the West of Scotland Research Ethics Service (Committee 5).

Thank you for reading this

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to take part in the ELIPSE study. Please ask us if you have questions or would like more information about the study.

Further information and contact details

If you have any questions or would like any more information, please contact:

ELIPSE Study Office
Centre for Healthcare Randomised Trials (CHaRT),
University of Aberdeen, Health Sciences Building
Foresterhill, Aberdeen AB25 2ZD
Tel: 01224 437263 or 01224 437490
Email: elipse@abdn.ac.uk
Web: **https://w3.abdn.ac.uk/hsru/ELIPSE**

The Chief Investigators for the study are Professor Krishna Narahari and Professor Rakesh Heer. You can contact them through the ELIPSE study office (details above).

If you wish to complain formally or have any concerns about any aspects of the way you have been approached or treated during this study, you can contact