The ELIPSE Study

A randomised controlled trial comparing the clinical and cost-effectiveness of lymph node removal in patients undergoing curative surgery for localised high-risk Prostate Cancer.

Participant Information Leaflet

Invitation to take part

We would like to invite you to take part in the ELIPSE study: a research study looking at two different types of surgery for prostate cancer. The study is funded by the National Institute of Health and Care Research (NIHR, the research arm of the NHS).

Before you decide if you would like to take part, we will explain why the research is being done and what it will involve.

The first part of this leaflet tells you the purpose of the study and what will happen to you if you take part. The second part gives you more detailed information about how the study is run.

Please take time to read the information carefully. It has been written with the help of men who have had surgery for prostate cancer. Feel free to talk to others about the study if you wish and to ask us if there is anything that is not clear or if you would like more information. There is more information on our website at https://w3.abdn.ac.uk/hsru/ELIPSE/Public/Public/index.cshtml

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

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

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. The operation (called a radical prostatectomy) involves removal of the entire prostate gland and, in some cases, removal of the nearby lymph nodes (which are part of the body's immune system).

Between 30-50% of men with high-risk localised prostate cancer get a recurrence of cancer, which means their cancer returns. Unfortunately, some of these men die from the cancer. There is no definitive evidence whether removing lymph nodes reduces the chance of cancer returning or not.

However, complications can occur after removing lymph nodes, including injury to nerves and blood vessels, fluid collecting at the operation site and blood clots. Sometimes this can cause pain, infection, swelling of the scrotum or legs, problems passing urine, and blood clots in the legs and/or lungs. Rarely, complications can be fatal.

About a third of men in the UK have lymph nodes removed during their surgery for prostate cancer. The operation is routinely carried out in hospitals around the UK. However, as explained above, there is no definite evidence to show which method (removing lymph nodes or not) is better.

We would like to do a new study to answer the question, *'Is removing these lymph nodes better than not removing them?*' The way we find this out is to do a clinical trial. The clinical trial is called the ELIPSE study. ELIPSE stands for **E**valuation of the role of **L**ymphadenectomy **I**n high-risk **P**rostate cancer **S**urg**E**ry,

The ELIPSE study will compare these two types of surgery:

- removal of the prostate with removal of lymph nodes
- removal of the prostate without removal of lymph nodes

To compare these two types of surgery, we will need to collect information (for 3 years) on a number of things, including any complications of surgery, quality of life and the results of any medical tests after surgery. The results of the ELIPSE study will help men with prostate cancer and their surgeons understand whether it is better to remove lymph nodes during prostate cancer surgery or not.

The study will run for 6 years and aims to involve 1080men from hospitals across the UK.

Why have I been chosen

This study is asking men to take part if they have recently been diagnosed with localised, high-risk prostate cancer, requiring surgery. Your surgeon and team have carefully considered your case. You are eligible for the ELIPSE study; and they would like to offer you the opportunity to take part.

What would taking part involve?

If you decide to take part, you will be randomly allocated (using a computer) to one of the two types of surgery mentioned above. 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 what type of surgery you are allocated to.

Either

- You will be in the group where the prostate and lymph nodes are removed; or
- You will be in the group where the prostate alone is removed.

There is an equal chance that you will be placed 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.

If you decide to take part, you should keep a copy of this leaflet and we will ask you to complete a consent form confirming that you are happy to take part. You can complete this consent form during a routine visit to the hospital or at home. If you complete the consent form at home you can send it back to us by post – after it has been signed by the researcher we will send you a copy back for your records. We will also ask you to complete a questionnaire (which should take about 15 minutes) about your quality of life and your recent contact with the NHS. If you complete the consent form at home, you can also complete the questionnaire at home and post this back to us with the consent form – you can do this before the researcher has signed the consent form.

Your surgical team will arrange a date for your surgery. If you have 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.

After you have had your operation we will collect some information from your medical records about the surgery you had. You will receive all the usual care within the NHS during your surgery and afterwards. 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.

As part of the ELIPSE study, we will follow you up for up to 3 years. The table below summarises what will happen while you are part of this research study. We will collect the rest of the study information from your usual NHS medical records.

	Complete a questionnaire	Questionnaire to complete
When you join the study	✓	Quality of life
3 months after surgery	✓	Quality of life, Time to return to normal activities, Harms
1 year after surgery	✓	Quality of life, Work productivity and impairment, Participant cost and resource use questionnaire, Participant time and travel, Harms, Further treatment
2 years after surgery	✓	Quality of life, Work productivity and impairment, Participant cost and resource use questionnaire, Harms, Further treatment
3 years after surgery	✓	Quality of life, Work productivity and impairment, Participant cost and resource use questionnaire, Harms, Further treatment

We will ask you to complete questionnaires about your recovery from surgery and your quality of life 3 months after your surgery. Some of these questions 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. After 1, 2 and 3 years we will ask about your quality of life, your use of healthcare services, any further treatment you have had for prostate cancer, any out of pocket expenses and whether your health impacts on work or regular daily activities. Each of these questionnaires will take about 15 minutes to complete. In the 1 year questionnaire, we will also ask you a few questions about your contacts with the NHS (for example how far it is to travel to your GP surgery or hospital) and how much it costs you to attend these appointments. This is so that we can understand the effect of the surgery on your time and costs. 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. 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.

We can send each of these questionnaires to you by post (along with a pre-paid envelope) for you to return them to the ELIPSE study office) or we can send you an email or text message (depending on your preference) with a link to complete the questionnaire online. We may send you reminders about completing the questionnaires to make sure relevant information about you is recorded for the study.

After your surgery, as part of standard NHS care, you will have regular blood tests to check your PSA. We will collect the results of these tests from your medical records.

After surgery, also as part of standard NHS care, you may sometimes have additional tests, based on your PSA results and condition after your surgery. You may also have more treatment. We will collect the results of the tests, investigations and additional treatments you have (up to 3 years after your surgery) from your medical records.

Before you have your surgery, if you, or the surgical team, decide that the type of surgery you were randomly allocated to is not right for you, alternative treatment can be planned. Whatever type of surgery you have, we would like to follow you up as part of the study.

We hope to be able to follow ELIPSE participants up for longer than 3 years by using data that is routinely collected in the NHS and death registration 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.

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.

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

We do not think that there are any possible disadvantages to you. Both types of surgery are already routinely being used in the NHS to treat patients with prostate cancer.

There are always risks associated with all surgical procedures. Steps are always taken to ensure that these risks are minimised.

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. Some of the main risks and benefits of each

type of surgery are described below. But, 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. Prostate doctors and nurses do not know which of the two options is best and that is why we are doing this study.

Surgery where lymph nodes are not removed	**Surgery where lymph nodes are removed**
There might be a higher chance of cancer relapse.	There might be a lower chance of cancer relapse.
There might be a lower chance of complications such as injury to nerves or blood vessels during the operation.	There might be a higher chance of complications such as injury to nerves or blood vessels during the operation.
There might be a lower chance of complications such as fluid collection or clots in legs or lungs needing treatment	There might be a higher chance of complications such as fluid collection or clots in legs or lungs needing treatment
This might reduce the time taken to perform your operation.	This might increase the time taken to perform your operation, meaning a longer general anesthetic.

Both treatments are safe - we are doing the study to find out whether removing the lymph nodes is better or not.

Do I have to take part?

No. It is entirely up to you whether or not 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

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.

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.

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.

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.

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.

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.

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.

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.

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

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.

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.

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), Health Services Research Unit University of Aberdeen Health Sciences Building Foresterhill Aberdeen AB25 2ZD Tel: 01224 437263 or 01224 437263 Email: elipse @abdn.ac.uk Web: **https://w3.abdn.ac.uk/hsru/ELIPSE**	**<<Local centre contact details>>**

The Chief Investigators for the study are Mr 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 <<local contact details for complaints>>.