<Local Hospital address>

PACE-NODES

A randomised trial of 5 fraction prostate stereotactic body radiotherapy (SBRT) versus 5 fraction prostate and pelvic nodal SBRT

We are inviting you to take part in a clinical trial called PACE-NODES

- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish.
- Take time to decide whether or not you would like to take part in this clinical trial. This decision is up to you. If you decide not to take part, this will not affect the care you get from your doctors in any way.
- You can decide to stop taking part in the study at any time, without giving a reason.
- Please just ask if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet for you to keep. You will also be asked to sign a consent form; you will get a copy of that to keep as well.

Important things that you need to know

Your doctor has explained to you that you have prostate cancer and you have been invited to participate in this clinical trial. Before you decide, it is important for you to understand why the research is being done and what it will involve. Participation is entirely voluntary. If you decide not to take part, your decision will be accepted without question, and your subsequent treatment will not be affected in any way.

Contents

How to contact us

If you have any questions about this clinical trial, please talk to your doctor or nurse. Their details are given on page 8 of the information sheet.

PART 1

1 Why am I being invited to take part?

You have been diagnosed with prostate cancer and a team of prostate cancer specialists feel that you would be suitable for both types of treatment (radiotherapy) in this study. This study is recruiting patients in a number of hospitals across the UK and also hopes to recruit patients in several other countries. We are aiming to recruit 1128 patients to the study. We need this many to participate in order to prove whether one type of radiotherapy is better than the other. You have been approached because your hospital doctor feels that you are suitable to take part.

2 What is the purpose of this study?

What is the trial looking at?

You have been invited to join this trial because you have localised prostate cancer that requires active treatment, your doctor will discuss all suitable options with you. We want to improve the treatment for patients who have 'high risk' localised prostate cancer, where there is a greater chance of the cancer returning. This is decided by your doctor on review of findings from your biopsy, Prostate-Specific Antigen (PSA) blood test and scans you will have already had to diagnose your prostate cancer.

We are proposing a clinical trial "PACE-NODES" testing an advanced type of external beam radiotherapy called stereotactic body radiotherapy (also known as SBRT) in 1128 participants with high risk localised prostate cancer. Importantly, this treatment delivers a potentially curative dose of radiotherapy in only five treatments over two weeks. Half the participants in the trial will have radiotherapy to the prostate, the other half will have radiotherapy to the prostate as well as the surrounding lymph nodes. We will follow patients in the trial for at least three and half years to see which treatment is best. We will be looking at whether it is safe to give this treatment by reviewing any side-effects that occur and also assessing whether giving SBRT to the lymph nodes as well as the prostate reduces the chance of prostate cancer returning.

What is stereotactic body radiotherapy (SBRT)?

SBRT (also known as SABR) is an advanced way of delivering radiotherapy (X-ray treatment), which can accurately deliver a high dose of radiotherapy to the prostate, in a fewer number of visits, also known as fractions. The treatment can be delivered on a linear accelerator or a Cyberknife platform. SBRT can reduce the dose to the surrounding tissues and has the added advantage of being more convenient for patients as there are fewer visits to hospital. From the completed PACE-B trial, which recruited 874 participants, we published the short-term side-effect results in 2019 and side effects at 2-years in 2022, showing this treatment is as safe as 20 visits. We also presented summary results in 2023 confirming that SBRT treatment is just as good at preventing prostate cancer from returning as the radiotherapy that would usually be given.

Why give pelvic lymph node radiotherapy?

Even though you have had a scan showing the cancer is not visible beyond the prostate, scans are not always helpful for detecting prostate cancer cells that have moved to the nearby lymph nodes. Patients with prostate cancer similar to yours may therefore benefit from having radiotherapy to the pelvic lymph nodes, in addition to treating the prostate. This includes the lymph nodes on the left and right side of the pelvis; these are located around the large blood vessels. This is an effective treatment for prostate cancer and may (or may not) be better than prostate only radiotherapy.

Radiotherapy to the prostate and lymph glands gives low levels of side effects but is normally given over several weeks. We have completed a single-centre study of 30 patients showing that radiotherapy to the prostate and lymph glands in five visits was achievable with acceptable side effects. We now need to test SBRT to the prostate and pelvic lymph nodes in high risk prostate cancer at multiple centres.

We will compare prostate and pelvic node radiotherapy with prostate only radiotherapy to see if it reduces the chance of prostate cancer returning**.** There might be an increased risk of side effects by treating the lymph nodes in addition to standard dose radiotherapy to the prostate and so this study will also investigate whether this is the case or not. We want to confirm the treatment is safe by looking at the short and long term side effects.

3 What will happen to me if I take part?

Before treatment

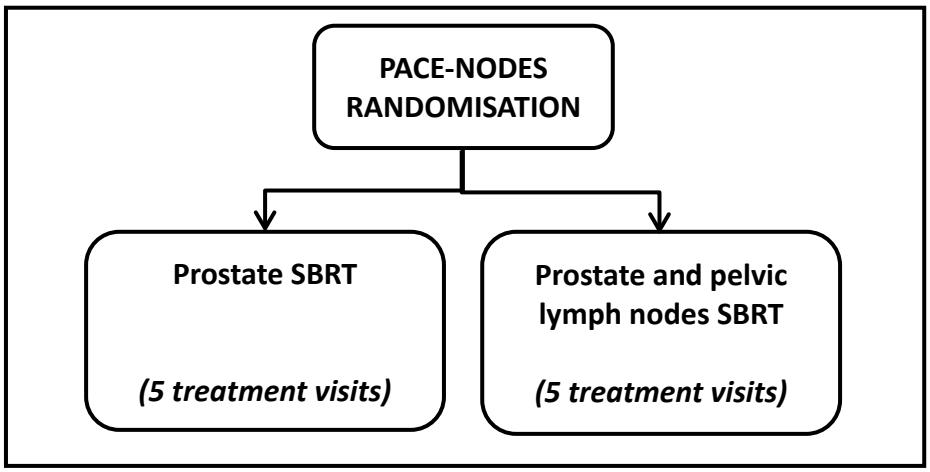
If you are interested in taking part you will want to speak to someone to make sure that you fully understand what will happen in this study. Your hospital doctor will give you this opportunity and if you agree to take part in this study you will be asked to sign a consent form.

Before starting your treatment, you will have some checks to make sure that both treatments are suitable for you. This will include a review of your medical history and medications. We will also check the test results you would have already had as part of your prostate cancer diagnosis to assess how advanced your prostate cancer is. This includes your biopsy results, MRI scan and a separate scan to check the cancer has not spread beyond the prostate. We will also ask you to fill in some detailed questionnaires about your current symptoms and your quality of life (further information regarding these questionnaires is given in Part 2 of this information sheet).

Which treatment will I receive?

Everyone who agrees to take part in this research study will be randomly allocated to one of two groups of patients. Half of the patients will receive SBRT to their prostate in five visits over 2 weeks, and half of the patients will receive SBRT to their prostate **and** pelvic lymph nodes in five visits over 2 weeks.

What treatment you receive is not decided by you, your doctor or any other person. The choice is made at random (by a computer) at the time you enter the study, the equivalent of tossing a coin. 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 the other group, it is more likely to be because of the treatment, rather than because the patients in one group are somehow different from those in the other group. You will be randomly allocated to one of the following:



The SBRT treatment will be given over five treatment visits (fractions) spread over two weeks (every other day). In both groups your prostate gland will receive a radiation dose of 36.25 Gray split over five fractions. If you are randomised to the pelvic lymph node radiotherapy group your pelvic lymph nodes will also receive a radiation dose of 25 Gray split over five fractions.

1) Prostate SBRT group: 36.25 Gray to the prostate split over 5 treatment visits on alternate days.

2) Prostate and pelvic lymph nodes SBRT group: 36.25 Gray to the prostate AND 25 Gray to the pelvic nodes split over 5 treatment visits on alternate days.

Both you and your treating team will be aware of the treatment that you have been allocated to.

Follow up

We will review you in clinic or by telephone at 2 weeks, 4 weeks, 8 weeks and 12 weeks after finishing treatment. After that, clinic/telephone appointments will then be every 6 months for 5 years. This long follow-up is needed to be absolutely sure about the effectiveness and side effects of the treatment.
At each clinic visit we will ask you about any symptoms you may have, and at some clinic visits we will ask you to fill in the quality of life questionnaire again.

4 What do I need to know about the treatments used in this study?

Hormone treatment

All patients will receive hormone therapy for between 12 and 36 months. This is standard treatment, that is, the same as you would receive if you weren't in this trial. Everyone will start hormone therapy before they start radiotherapy and continue after the radiotherapy. You may have already started this treatment. Hormone therapy works by preventing the hormone testosterone from feeding the prostate cancer cells. Please discuss any questions about hormone therapy with the doctor looking after you.

Method for targeting the prostate

All patients receive radiotherapy with 'daily image guidance' which means that we check the position of the prostate gland before each radiotherapy fraction to improve the accuracy of radiotherapy. The image guidance can be done with a number of different techniques including special CT scans (cone beam CT), gold markers (fiducial markers) or MRI; your doctor will explain which one is used at your hospital.

If your hospital uses gold markers (fiducial markers) you will have a day procedure to position the markers into the prostate. This usually takes about 15 minutes and you can go home straight afterwards. Some patients experience some bleeding after the procedure, in the stools, urine or semen. There is also a small risk of infection, because of this you will usually be given some antibiotics to use before and after the procedure. The procedure may be painful or uncomfortable. The markers stay in the prostate forever and do not cause any problems in the long term.

Radiotherapy treatment - SBRT

SBRT treatment will be given in 5 sessions, every other day over 2 weeks. The length of each treatment session depends on the type of machine at your hospital, but will range between 10 and 60 minutes each day. The radiographer will position you on the couch and ensure that you are comfortable. We will ask you to stay as still as possible on the treatment couch, and the radiotherapy machine will move around you without touching you. You will not feel anything - it is similar to having an x-ray.

Side effects

All treatments may cause side effects.

The risks and side effects of standard radiotherapy are well known and will be explained as part of the informed consent process. SBRT is not usually standard of care in the UK at the present time and there may be some side effects which are more or less common than standard radiotherapy.
Radiotherapy treatment can cause side effects because the healthy tissues in the pelvis (mostly the bladder and bowel) are exposed to the radiation. Radiotherapy can occasionally cause you to feel more tired than normal. Most patients experience some side effects but nearly all of these are temporary. At two years after radiotherapy, around 1 in 20 (5%) of patients have ongoing noticeable side effects; in total around 1 in 8 (12%) may be affected at some point.

It is important that you tell your study doctor or nurse about any problems you have at each hospital visit, so that appropriate action can be taken. You can contact your doctor or nurse between visits if you are concerned. Their numbers are on page 8 of this information sheet.

Common side effects during and immediately after radiotherapy treatment

(Most patients (>50%) will experience one or more of these):

- Tiredness
- Loose bowel motions or diarrhoea
- Discomfort in the back passage
- Needing to pass water more frequently
- Needing to pass water more urgently
- Discomfort on passing water

Rare side effects during and immediately after radiotherapy treatment

- Skin redness
- Temporary loss of pubic hair
- Small risk of needing a urinary catheter (1-2% risk)
- Lymphoedema (<1% risk)

Common side effects in the long term

(occurring in the months and years after radiotherapy treatment):

- Impotence or change in sexual experience (about 50% risk)
- Infertility (almost 100% risk)
- Minor change in bowel habit (around 30% risk)
- Minor change in urinary function (about 50% risk)

Rare side effects in the long term

(Likely to affect less than 1 in 10 patients; occurring in the months and years after radiotherapy treatment):

- Narrowing of the urethra (tube to the bladder) causing problems passing water (<5%)
- Moderately bothersome change in bowel habit (up to 10 % patients over 5 years)

- Bleeding from the back passage needing surgical treatment (<5%)
- Bowel or bladder incontinence (<1%)
- Severe bleeding upon urination (<1%)
- Possible very small increase in the risk of rectal (bowel) or bladder cancer (<0.5%)
- Risk of damage to the bones of the pelvis (<0.5%)
- Risk of damage to the nerves of the pelvis (<0.5%)

Bowel side effects: During radiotherapy there may be an increase in the frequency and urgency of bowel movements with passing of mucus. After treatment, symptoms are expected to substantially settle within 4-8 weeks but some degree of urgency and looseness may persist. Rectal bleeding is usually slight but may occur in approximately one out of 10 patients treated. The majority of patients do not need any treatment for bleeding, however it may be necessary to investigate this, in case it is due to a different problem. In addition, rectal discomfort may occur in fewer than 2 out of 10 patients during and after radiotherapy treatment.

Bladder side effects: It is quite common for patients to urinate more frequently and/or urgently during radiotherapy, sometimes with discomfort. These side effects usually subside within 4-8 weeks of treatment finishing, and commonly any remaining symptoms are less than those reported before radiotherapy started. However, a small proportion will continue to have increased frequency or urgency. Urinary incontinence is rare. In addition, fewer than 2 out of 10 patients will experience slight blood loss whilst urinating during and after radiotherapy. This should be investigated in case it is due to a different problem. Rarely, patients develop a narrowing (stricture) of the water tube (urethra) inside the prostate. This leads to a poor urine stream which might require a stretching procedure.

Sexual impotence and fertility: Sexual activity is likely to be significantly impaired during hormone and radiotherapy treatment but may recover in about 30-50% of cases after radiotherapy. Patients treated with over 6 months of hormonal therapy, as for this trial, will take longer to recover sexual function. Those with difficulties before treatment have more difficulties after radiotherapy. If you would like to maintain sexual function it is important to try to do this as soon as possible after your hormone treatments have worn off, using Viagra or Cialis if needed. We expect patients to become infertile after radiotherapy treatment but please see guidance below regarding contraception (section *'What do I have to do?').*

Long-term risks: The radiotherapy and associated scans that you will receive are part of your routine care. If you take part in this study, you will not undergo any additional exposure to radiation over and above standard practice, but the state-of-the-art image-guided radiotherapy will be delivered differently to standard practice in the UK. These procedures use ionising radiation: x-rays or gamma rays to form images of your body, x-rays to ensure targeted treatment delivery, and higher energy radiation for your radiotherapy treatment. Ionising radiation can alter the way cells work, which may lead to a very small increase in the risk of developing a further cancer in the years or decades after radiotherapy. There is always a chance of this occurring with any radiotherapy treatment (whether this is part of a study or not).

Hormone treatment: Hormone treatments work by lowering testosterone levels, or blocking testosterone from working. This may cause tiredness, reduction in muscle strength, hot flushes, depression, decreased sex drive (loss of libido) and impotence, and occasionally a small amount of

breast tissue swelling and tenderness. Receiving hormone treatment over a long period of time can cause a weakening of your bones (in severe cases this is called osteoporosis). You may also notice you gain weight and lose muscle mass. There may also be an increased risk of developing diabetes and heart disease.

What do I have to do?

Hospital visits: You will have to visit the hospital to receive your treatment and other tests. You will also have to see your doctor for follow-up visits after treatment has been completed. At some of the visits, you will be asked to complete quality of life questionnaires (see Part 2 of this information sheet).

You will not be paid for taking part in this study but some hospitals may be able to help arrange transport for your hospital visits. Please check with your doctor if this is available at your hospital.

Contraception: During treatment and for one year afterwards, your sperm may not be formed normally or not produced at all. If applicable, you or your partner should use effective contraception during this period, i.e. two forms of contraception, one of which must be a condom. If your partner does become pregnant during the course of the study, you must tell your doctor.

5 How to decide whether to take part in this study?

What are the benefits and risks of taking part?

Taking part in this trial means that you will receive an advanced treatment which delivers a high dose of radiation to the prostate with relative sparing of surrounding healthy tissue.

The information we get from this study will help us to improve the future treatment of patients with prostate cancer. Although by taking part in the study you may not directly benefit, it will help to answer these questions and hopefully improve treatment for prostate cancer patients like you in the future.

You may have side effects associated with treatment given in this study. Most of these are listed above, but there may be others that we cannot predict. Side effects will vary from person to person in terms of severity and type, so you are encouraged to report anything you notice to your doctor or team members involved in the trial.

Patients who receive treatment to the pelvic nodes in addition to the prostate may experience more of these side effects in the short or longer term, this is because a larger area is receiving radiotherapy. Your radiotherapy team will be monitoring you closely in clinic and will help you to manage any side effects that develop, this may include the use of additional medications.

Because we want to check that this treatment is safe, as a result of your participation in this study, we will speak to you more frequently than usual, to check up on your progress. Some of the appointments can be done on the telephone. We have tried to schedule subsequent follow up appointments at the same time as most hospitals would see you. Your doctor will explain if any visits in this study are additional to standard follow up at your hospital.

If you have private medical insurance, please ensure that your insurers are aware that you are considering joining the trial and that it does not adversely affect any claim you may have.

Do I have to take part in the study?

No, you do not have to take part; it is up to you to decide. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What are the alternatives for treatment?

If you decide not to participate in this trial, you will be offered standard radiotherapy. It is important that you only enter this trial if you are prepared to accept either of the treatments.

What if there is a problem?

Any complaint about the way you have been dealt with during this study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2 of this information sheet.

What if new information relating to the study becomes available?

Sometimes, during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your doctor will make arrangements for your care to continue. If you decide to continue in the study you may be asked to sign an updated consent form. Also, on receiving new information your doctor might consider it to be in your best interests to withdraw you from the study. If this happens, they will explain the reasons and arrange for your care to continue.

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2 of this information sheet.

Contact details

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

Local Consultants name: Address, Telephone, E-mail [details to add]

Local Nurse name: Address, Telephone, E-mail [details to add]

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

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

1 Quality of life study

If you decide to take part in the PACE-NODES study, we would like you to ask you some questions about the way you feel, both physically and emotionally. These are termed "Quality of Life" questionnaires. These will help us to understand about the impact of any side effects you might have.

If you agree to take part in the Quality of Life study, you will be asked to fill in some short questionnaires asking about your quality of life and general health. We will ask you to fill in a questionnaire before you are told which treatment group you are allocated to, and then after your treatment has finished at week 4, month 6, month 12, and year 5.

You will be given your first questionnaires in clinic. After the 6 month hospital appointment we will send them to you at your home address. We will check with your GP and/or hospital doctor beforehand that you are well. The questionnaire should take about 20 minutes to complete. The answers you give to the questions are for the PACE-NODES Trial Quality of Life Study only and will be treated in the strictest confidence. This means your hospital will not know how you have answered, so if you are having any problems you still need to tell your doctor

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 answer them as best you can.

The questionnaires do include some questions that may make you feel uncomfortable or upset, especially those regarding sexual function and continence. Whilst we don't want to make you feel uncomfortable or embarrassed, these questions address important areas of men's health that we aim to investigate as part of the study outcomes. The information you provide in the Quality of Life study will be treated in the strictest confidence. If you subsequently change your mind and do not want to take part in the Quality of Life study you can still take part in the main PACE-NODES study.

2 Tissue collection

Part of your cancer will have been sampled (biopsied) before this study has been discussed with you, to establish your diagnosis. These samples are routinely stored (in a block of paraffin wax) in the pathology department of your hospital, after it has been examined to give the diagnosis. We would like you to agree to the donation of some of this stored tissue for future research. You will not need to undergo any more surgery for this – we are just using tissue that has already been taken.

Your tissue samples will be sent to a UK central research laboratory and will be identified by your trial number, initials and date of birth only. The samples will then be given a unique identification number and will be stored strictly in accordance with national guidelines.

We would also like to be able to make your samples and any information necessary for their analysis available to other researchers for future medical research. This could also include genetic testing. It is possible that the future research will be carried out outside of the UK, both in Europe and the US. Any future research using your tissue must be approved by an independent Ethics Committee before it is allowed to go ahead. Any samples and information transferred to third parties will not contain your personal information, so they will not be able to identify you from the information provided.

It will not be possible to release the results of future tests carried out on your samples to you or your research doctor and they will not form part of your medical records.

This donation is optional, and your treatment will not be affected if you choose not to give these samples.

3 Confidentiality

How will the information about you be used?

The Institute of Cancer Research is the sponsor and will act as the data controller for this study based in the United Kingdom. This means that the ICR are responsible for looking after your information and using it properly when you have agreed to take part.

The ICR'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. The procedures for handling, processing, storage and destruction of your data will be compliant with the Data Protection Act 2018 and in accordance with the UK Policy Framework for Health and Social Care Research.

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

This information will include your initials, full name, hospital number, date of birth, postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland). This information will be entered onto the ICR's clinical trial database, managed and maintained by us. Your information will be used to conduct the research and to check your records to make sure that the research is being done properly. At any time for purposes associated with our research, authorised people may look at your information, this includes people within the ICR and the RMH as well as regulatory authorities, Collaborators or other third parties approved by ICR which may have offices outside of the UK or Europe.

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 Study number instead. We will keep all information about you confidential, safe and secure.

The information collected will be kept by the ICR for at least 5 years and by the [insert appropriate name for NHS site] for at least 5 years after the study has closed.

As you will be receiving radiotherapy in this study a copy of the imaging (such as CT, MRI scans) used to design your treatment plan will be sent to the Radiotherapy Quality Assurance team. 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. 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.

You can stop taking part in the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage our records in specific ways for the research to be reliable and accurate. This means that your rights to access, change or move your information is limited. To safeguard your rights, we will use the minimum personally-identifiable information possible.

From time to time, we would like to know how you are getting on. Ideally, we would like to do this for life using national records which are kept on everyone's health status. One of these is held at the General Register Office (GRO). We will need to give them enough information to identify you. This usually includes 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 study. Please initial the consent form to show that we have your permission to do this.

For the purposes of our research, de-identified information about you including your samples or scans may be transferred to researchers within or outside the UK and European Economic Area with appropriate safeguards, now or in the future. Some countries outside the UK and Europe may not have laws which protect your privacy to the same extent as the Data Protection Act in the UK or European Law. 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. We will take all reasonable steps to protect your privacy. 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.

Where can I find out more about how my information is used?

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

- at https://www.icr.ac.uk/legal/privacy
- by sending an email to ICR's Data Protection Officer at dataprotectionofficer@icr.ac.uk
- at www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency
- at www.hra.nhs.uk/information-about-patients

4 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). Ask your team how you can contact the PALS team if you would like to discuss any issues.

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 care 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.

What will happen to the results of the research study?

Independent experts will review the progress of the research, and the results will be published in a medical journal as soon as there is enough information to be sure the results are reliable. You will not be identified in any report or publication. The results will help to decide how to treat prostate cancer

in the future. The results of this study are not likely to be available for at least 7 years, but some data may be available sooner. If deemed appropriate at the time that the results are available, your hospital will write to you when the results are known to ask if you or a family member would like to see them. The letter will explain how to get a copy.

Who is organising and funding the research?

The sponsor of this study is the Institute of Cancer Research. The trial is financially supported by Prostate Cancer UK. PACE-NODES is part of the UK National Cancer Research Network portfolio.

Your doctor will not receive any personal payments for including you in this research study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. The study has been by approved by the London-Chelsea Research Ethics Committee.

What do I have to do now?

You will have some time to think about the study and make your decision. You may wish to discuss it with your family or friends. Please keep this information sheet and copies of the signed consent form. If, at any time, you have any questions about the study you should contact your hospital doctor.

5 Contacts For Support

Who else can I contact for further information?

You have the right to ask questions about this study at any time and are encouraged to do so. You can call the study doctor or hospital if you feel that you are developing any unwanted side effect, or if you believe you have been injured as a result of your receiving study treatment, or if you have any questions about this study or your participation in this study.

Your study doctor is: _____

Your study nurse is: _____

Contact phone numbers: _____

Out of Hour Numbers: _____

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

Thank you for interest in our research.