<Local Hospital address>

CANCER RESEARCH UK

ICR The Institute of Cancer Research

PIVOTALboost

A vs B vs C2 vs D2 randomisation

(Pelvic lymph node radiotherapy and HDR boost brachytherapy)

We are inviting you to take part in a clinical trial called PIVOTALboost

- 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'll 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 has invited you 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. This sheet should be read with the "General Patient Information Sheet - Part 2" and the local HDR brachytherapy leaflet.

Contents

Part One

1 What is the purpose of this study?
2 What are the treatments being tested in this study?
3 Why am I being invited to take part?
4 What will happen to me if I take part?
5 What do I need to know about the treatments used in this study?
6 How to decide whether to take part in this study?

Part Two

1 Quality of Life study
2 Tissue collection
3 Confidentiality
4 Further information
5 Contacts for support

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 What is the purpose of this study?

Patients with prostate cancer similar to yours may benefit from pelvic node radiotherapy or dose escalated radiotherapy with HDR brachytherapy (internal radiation). These are effective treatments for prostate cancer and may (or may not) be better than standard prostate only radiotherapy. This is because there is a chance in your case that the cancer may have spread from the prostate to the pelvic lymph nodes (although there is nothing visible on your prostate staging scans). This study will investigate the benefit of whether in addition to treating the prostate gland with radiotherapy, the lymph nodes in the pelvis are also included within this treatment (called **Pelvic lymph node radiotherapy).** In addition, you may be offered **brachytherapy** (internal radiation) to the whole prostate which includes a boost to the area in the prostate where the tumour is located. This treatment delivers a high radiation dose to the prostate. It is combined with external beam radiotherapy.

There might be an increased risk of side effects with these treatments (Pelvic lymph node radiotherapy and brachytherapy) compared to standard dose radiotherapy to the prostate and so this study will also investigate whether this is the case or not.

This study is taking part in a number of hospitals across the UK. Approximately 1952 men will be invited to take part.

2 What are the treatments being tested in this study?

Prostate radiotherapy combined with pelvic lymph node radiotherapy and HDR brachytherapy with a boost have been tested in large groups of patients but it is uncertain whether they may or may not be better at reducing the chance of cancer coming back after treatment. All treatment options include radiotherapy to the prostate and may include pelvic lymph node radiotherapy and / or HDR brachytherapy with boost.

Pelvic lymph node radiotherapy

Patients who may have spread of their cancer to pelvic lymph nodes may benefit from pelvic lymph node radiotherapy which includes the lymph nodes on the left and right side of the pelvis; these are located around the large blood vessels. The treatment is planned with Intensity Modulated Radiation Therapy (IMRT). IMRT shapes the radiotherapy beams to avoid surrounding organs like the bowel, but there is still a small risk of increased bowel side effects. We will compare prostate and pelvic node radiotherapy with prostate only radiotherapy to see if it reduces the chance of prostate cancer returning.

HDR brachytherapy

Brachytherapy to the whole prostate with a boost to the tumour area is also called high dose rate (HDR) brachytherapy. This treatment delivers a high radiation dose to the prostate. You will be admitted for the procedure, which is performed under an anaesthetic. Please refer to

the specific local leaflet for more details. It is combined with external beam radiotherapy to the prostate (15 fractions) or to the prostate and pelvic lymph nodes (20 fractions).

3 Why am I being invited to take part?

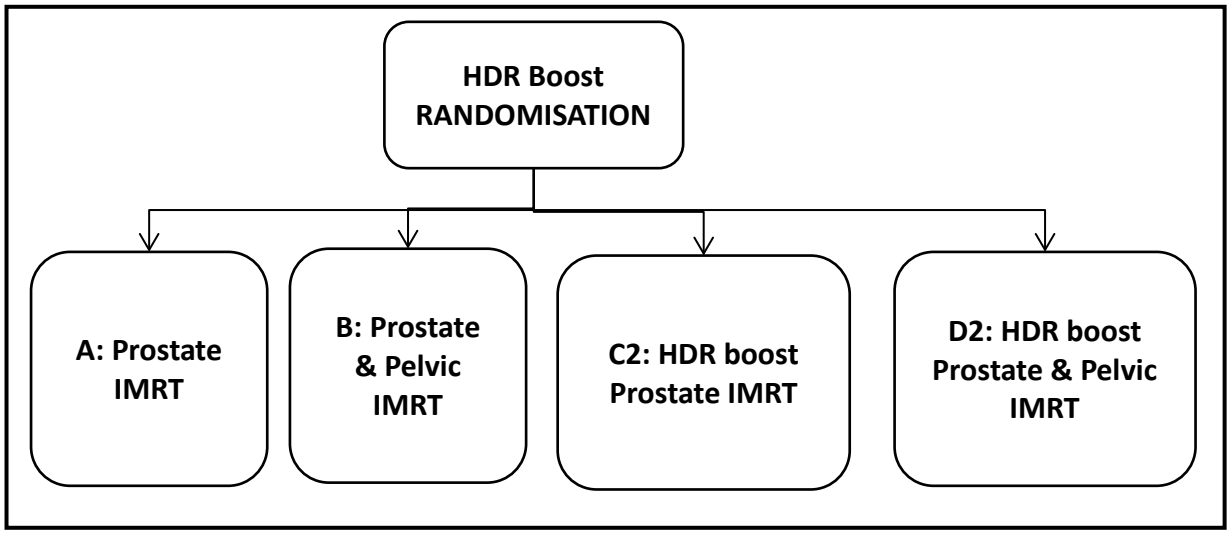
You have been diagnosed with a type of localised prostate cancer that can be treated with radiotherapy. All patients approached about this study have no spread outside the prostate visible on their staging scans. Your doctor feels that you are suitable for treatment in this study.

4 What will happen to me if I take part?

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.

All patients in the trial will undergo the standard staging tests (blood tests, MRI scan and bone imaging of the bones) before they can take part in the trial. You may have already had these tests as part of your diagnosis. All patients will receive hormone therapy for 6 months or 2 years according to standard treatment. Everyone will start hormone therapy about 2 - 4 months 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 reaching the prostate cancer cells. Please discuss any questions about hormone therapy with the doctor looking after you.

If you decide to take part in the trial, you need to sign a consent form. 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 the 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 from those in the other groups. You will be randomly allocated to one of the following:



A Prostate IMRT: The whole prostate gland will receive a radiation dose of 60 Gray in 20 fractions. Gray (Gy) is the dose of radiotherapy. The treatment is given every weekday for 4 weeks.

B Prostate and pelvic IMRT: The whole prostate gland will receive a radiation dose of 60Gy in 20 fractions. The pelvic lymph nodes will receive a dose of 47Gy in 20 fractions at the same time as the prostate is treated. The treatment is given every weekday for 4 weeks. Outside the trial most hospitals use a 6.5 - 7.5 week schedule (32-37 fractions) to treat pelvic lymph nodes. In previous studies, 20 fractions have been used to treat pelvic lymph nodes and this was found to be tolerated well by patients but is not currently standard of care. Therefore, you will be monitored for any side effects treated in the PIVOTALboost trial very carefully.

C2 HDR boost brachytherapy combined with prostate IMRT: The HDR brachytherapy will be delivered in a single fraction. The whole prostate will receive 15Gy and the area of the tumour will receive 19Gy. In addition, the whole prostate gland will receive a radiation dose of 37.5Gy in 15 fractions. The treatment is given every weekday for 3 weeks.

D2 HDR boost brachytherapy combined Prostate and pelvic IMRT: The HDR brachytherapy will be delivered in a single fraction. The whole prostate will receive 15Gy and the area of the tumour will receive 19Gy. In addition, the whole prostate gland will receive a radiation dose of 42Gy in 20 fractions. The pelvic lymph nodes will receive a dose of 47Gy in 20 fractions at the same time as the prostate is treated. The treatment is given every weekday for 4 weeks.

Follow up

You will be seen regularly by your doctor and/or nurse after treatment. You will be seen at 6, 8, 12, 18 weeks, and 6 months, then 6 monthly to year 2, then yearly to year 10. At these visits your doctor will manage and record any side effects you may be having and check up on your progress. You have a routine blood test (PSA) 18 weeks after you start radiotherapy, and then at 6-monthly intervals from 6 months for 2 years and yearly thereafter.

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

Radiotherapy planning. The IMRT is planned with a CT scan. A CT scan can reveals anatomical details of your prostate and the organs surrounding it that cannot be seen on conventional X-rays. The radiographer will explain the procedure to you. You may get an injection of contrast dye (to improve the visibility of the pelvic nodes) before the CT scan if you are allocated to pelvic node radiotherapy. You will get a list of your treatment dates from the research team and you can go home. You will start your radiotherapy treatment 2-3 weeks later.

Image guided radiotherapy. All patients receive radiotherapy with daily image guidance as this will improve the accuracy of radiotherapy: we check the position of the prostate gland before each radiotherapy fraction. This can be done with a number of different techniques and your doctor will explain which one is used at your hospital. This can be dose with special CT scans (cone beam CT), ultrasound scans or fiducials markers. If your hospital uses gold markers then this procedure usually takes about 20 minutes and you can go home straight afterwards. Most patients experience some bleeding after the procedure, in the stools, urine or semen. There is also a small risk of infection. Because of this we may give you some antibiotic tablets to take before and after the procedure and also an antibiotic suppository just before the procedure. The procedure may be painful or uncomfortable for a day or so. The markers stay in the prostate forever, and do not cause any problems in the long term.

Radiotherapy Treatment. Your radiotherapy treatment will be given in 20 sessions, every weekday for four and a half to five weeks. For HDR brachytherapy in combination with prostate only radiotherapy you only have 15 treatments. Each treatment session will take 10-15 minutes. For this the radiographer will position you on the couch and ensure that you are comfortable ready for your treatment. The radiotherapy treatment only takes a few minutes, but you will need to lie still for approximately 10 minutes whilst we check the prostate position and the machine moves to deliver the treatment from different angles. You will not feel anything - it is similar to having an x-ray. During radiotherapy treatment you will be seen by your doctor and/or nurse every week to manage any side-effects you may be experiencing.

HDR boost brachytherapy. The procedure is very similar to HDR brachytherapy without a boost. You are admitted to hospital either as day case or overnight. In theatre, you either have a general anaesthetic or an epidural anaesthetic. The procedure depends on the local HDR system, so please refer to the local information leaflets. Most patients have blood in the urine at the end of the HDR treatment, so you need an indwelling catheter until this settles. Once you can pass water normally, you will be able to go home.

Side effects

All treatments may cause side effects.

Hormone treatments work by lowering testosterone levels. This may cause tiredness, reduction in muscle strength, hot flushes, decreased sex drive (loss of libido), and occasionally a small amount of breast tissue swelling. If you receive hormone treatment over a long period of time it can cause a weakening of your bones (in severe cases this is called osteoporosis). You may also notice you gain weight and lose muscle. There may also be an increased risk of developing diabetes and heart disease.

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 also cause you to feel more tired than normal. Most men experience some side effects but nearly all of these are temporary. Two years after radiotherapy, around 5% of patients have ongoing noticeable side effects; in total around 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 telephone your doctor or nurse between visits if you are concerned. Their numbers are on page 8 of this information sheet.

Bowel side effects: During radiotherapy there may be an increase in the frequency and urgency of bowel movements with passing of mucus. Bleeding is uncommon during radiotherapy. After treatment, symptoms are expected to substantially settle within 4-12 weeks but some degree of urgency and looseness may persist. Rectal bleeding is usually slight but may occur in approximately one man out of 10 treated. Bleeding most commonly occurs 18-24 months after radiotherapy; it is less common later on. The majority of men do not need any treatment for bleeding. In addition, rectal or lower abdominal discomfort may occur in fewer than 2 out of 10 men 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 4-12 weeks of treatment finishing, and commonly any remaining symptoms are less than those reported before radiotherapy started. However, a small proportion of men continue to have

frequency or urgency. Urinary incontinence is rare. In addition, fewer than 2 out of 10 men will experience slight blood loss whilst urinating during and after radiotherapy. 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 50- 60% men after radiotherapy. Men treated with over 6 months of hormonal therapy may take longer to recover sexual function. Men with difficulties before treatment have more difficulties after radiotherapy. We expect men to become infertile after radiotherapy treatment. However we strongly recommend that you or your partner should use effective contraception. See section *'What do I have to do?'*

Long-term risks: You are undergoing Radiotherapy as part of your care which is a form of ionising radiation. If you take part in this study the radiotherapy you receive may be different to standard radiotherapy.

Ionising radiation can cause cell damage that may, after many years or decades turn cancerous. Taking part in this study will not significantly alter the chances of this happening to you.

What do I have to do?

Hospital visits: You will have to visit the hospital to receive your treatment and other tests. If you wish, you are welcome to bring a friend or relative to the visits. You will also have to see your doctor for follow-up visits after trial treatment has been stopped. **At some of the visits, you will be asked to complete quality of life questionnaires (see Part 2 of this information sheet),** which should take about 20 minutes to complete.

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.

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

What are the benefits and risks of taking part?

All patients in the trial will be treated with high quality technical advanced radiotherapy designed by a group of leading experts in the field of prostate radiotherapy. It is hoped that there will be improved tumour control if the radiotherapy of the pelvic lymph nodes is more effective than just treating the prostate. Improved tumour control might lead to a lower use of treatments for recurrent cancer and improved survival.

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 men like you in the future.

If you are allocated to prostate and pelvic node radiotherapy, you may receive an extra injection of intravenous contrast to help design your radiotherapy. Please let the radiographer know if you ever had any problems after contrast injections. The pelvic node radiotherapy may have an increased risk of side effects (loose motions and diarrhoea), because more bowel will be exposed to radiotherapy compared to standard treatment. We will try to minimise these risks, but treating larger areas can have more side effects. If you have HDR boost brachytherapy, you may have blood in your urine for a few hours afterwards and some bruising and discomfort. This tends to settle in a few days. The HDR boost brachytherapy may have increased bladder or bowel side effect because the base of the bladder, the urethra (tube between bladder and penis) and the lower rectal wall may be exposed to a higher radiotherapy compared to standard treatment. The exact risks will depend on the position of the boost volume and the doctor will explain this to you. We will try to minimise these risks, but treating with a higher dose can have more side effects.

Because of your participation in this study, you will need to visit your hospital to check up on your progress more often, during the first 3 months after you finished your radiotherapy treatment. Some of the appointments can be done on the telephone. We have tried to schedule subsequent follow 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.

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, you will be asked to sign a consent form but you are free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive. Once you have started radiotherapy, it is advisable to continue treatment as prescribed regardless what treatment arm you have been allocated to; any interruption is likely to make radiotherapy less effective.

Will I be asked to do anything else?

If you agree to take part we will ask you whether you would like to take part in a Quality of Life study and Tissue collection. These optional substudies are explained fully in Part 2 of this information sheet.

What are the alternatives for treatment?

You and your hospital doctor should have discussed the treatment options available to you. Your hospital doctor should discuss with you all your available treatment options before you decide if you want to take part in this study. Alternatives to radiotherapy include treatment with surgery (e.g. prostatectomy), radioactive implants (e.g. insertion of radioactive seeds) , or close observation with later treatment if necessary (e.g. active surveillance).

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, he/she 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 sub study

If you decide to take part in the PIVOTALBoost study, we would like you to complete questionnaires as we would like to find out about any side-effects you have and the way you feel, both physically and emotionally.

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 randomised, at the end of your treatment and then at week 6, 8, 12, 18 and then at months 6, 12, 18, 24, and then yearly until year 5.

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 the clinic. After the 6 month 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 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 PIVOTALboost study.

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.

2 Tissue collection

Part of your cancer (biopsy) will have been removed 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, even after it has been examined to give the diagnosis. You will not need to undergo any more surgery for this – we are just aiming to use what has already been taken. We would like you to agree to the donation of some of this stored tissue for future research. Your tissue samples will be sent to an accredited UK research laboratory and will be identified by your trial number, initials and date of birth only. They 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 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

The Institute of Cancer Research is the Sponsor for this study based in the United Kingdom. We will be using information from you and/or 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 20 years after the study has finished.

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.

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

[NHS site] will use your name, NHS number and contact details 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. Individuals from The Institute of Cancer Research and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [NHS site] will pass these details to The Institute of Cancer Research along with the information collected from you and/or your medical records. The only people in The Institute of Cancer Research who will have access to information that identifies you will be people who need to contact you to send a Quality of Life booklet by post or audit the data collection process.

[NHS site] will keep identifiable information about you from this study for 20 years after the study has finished.
You will be given a unique registration number, which will be used together with your initials and date of birth on forms that the research staff send to the trials office. All information about you 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.

We will be contacting your hospital from time to time to find out how you are getting on. Ideally we would like to do this for a long time, but patients sometimes change address and/or

GP or lose touch with their hospital. If this happens we would like to use national records which are kept on everyone's medical history to find out how you are and to collect some basic information about your health. We will need to give the organisations that hold these records enough information to identify you. This is usually your name, date of birth and NHS number (or Community Health Index 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.

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

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. 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.

Data sharing

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. 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.

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).

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.

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 5 years. 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 research study is being carried out by a network of doctors across the UK. The trial is co-ordinated by the Institute of Cancer Research. The research is approved and funded by Cancer Research UK.

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

Who has reviewed the study?
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 consultant.

5 Contacts for support

CancerBACKUP is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. They have published useful booklets about (1) prostate cancer (2) radiotherapy, and (3) clinical trials in general. 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).

Further information: 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.

Thank you for interest in our research.