

A guide to prostate cancer clinical trials

This fact sheet is for anyone affected by prostate cancer who would like to know more about clinical trials. It describes different types of trial and what taking part in one involves. It also tells you where you can find details of current trials and where to get further information and support.

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What is a clinical trial?

A clinical trial is a type of medical research study that aims to find new and improved ways of preventing, diagnosing, treating and controlling illnesses. Clinical trials are done for all types of illnesses but in this fact sheet we are concentrating on clinical trials for prostate cancer.

Clinical trials involve testing new medicines and procedures on people in a controlled and carefully planned way. Clinical trials are the best way to find out whether a new treatment is better than the current standard treatment. They can also find out if existing treatments work better in new combinations or doses. Some clinical trials find out more about the psychological and social effects of illness and treatment.

Why are trials done?

Clinical trials aim to answer specific questions about a treatment or procedure, such as:

- Is it effective?
- Is it safe?
- Does it cause side effects?
- Does it work better than existing treatments?
- Will it impact on quality of life?

Who works on trials?

The research team will normally include doctors, nurses, scientists who design the trial and other health professionals such as radiographers.

What are the different types of prostate cancer trial?

These are some of the areas that clinical trials for prostate cancer investigate:

- Prevention - whether drugs, vitamins, diet or exercise can reduce men's risk of prostate cancer.
- Screening - the benefits and risks of a national screening programme where lots of men are tested for prostate cancer. You can read more about screening in our booklet, **Understanding the PSA test: A guide for men concerned about prostate cancer.**

- Diagnosis - trying out new tests or scans to make the diagnosis of prostate cancer more accurate. For example, developing better ways to work out how aggressive the prostate cancer is and whether it may spread.
- Treatments - many clinical trials for prostate cancer investigate new treatments or new ways of using existing treatments. For example, at the moment trials for prostate cancer treatment are investigating: different doses of radiotherapy, new techniques for surgery (radical prostatectomy), combining treatments such as hormone therapy and radiotherapy and developing new drugs to treat advanced prostate cancer that is no longer responding to other treatments.
- Quality of life - most trials look at how prostate cancer or its treatment affects you and your daily life. For example, a trial may look at ways of controlling side effects of treatment, such as urinary problems.

Phases

There are four phases of clinical trials - phases 1, 2, 3 and 4. You may also see these written with Roman numerals - phase I, II, III and IV.

- Phase 1 trials aim to find out about safety and side effects. If the new treatment is a drug, the research team will work out the best dose to use.
- Phase 2 trials start to look at how well a treatment works. Only treatments that have got through phases 1 and 2 go into phase 3 testing.
- Phase 3 trials test a new treatment against the best existing (standard) treatment. Phase 3 trials normally involve many more people than phase 1 or 2 trials, sometimes thousands.
- Phase 4 trials are carried out after a new treatment is in use. They collect information about long term risks and benefits of a new treatment.

Randomisation

All phase 3 trials and some phase 2 trials are randomised. This means that the people taking part in the trial are randomly put into different groups (usually two). One group will

have the new treatment and one will have the standard treatment and the research team will compare the results.

Neither the research team nor the participants have a say about who goes in which group. It is decided randomly, usually by a computer program. One reason why trials are randomised is because, if the research team decided who should get which treatment, they might be influenced by what they know about their patients. They might put people who they thought were healthier or more unwell into a particular group. This would make the results of the trial unreliable.

Placebo

A placebo is a dummy treatment, for example a sugar pill that looks the same as a new drug being tested. Research teams use placebos to protect against 'the placebo effect.' This means that people getting a treatment might just be feeling better because they know they are having treatment, even if the treatment does not really work.

Placebos are not used in many clinical trials and even less commonly used in cancer clinical trials. This is because it is difficult to create 'dummy' surgery or radiotherapy and because the side effects of drugs like hormone therapy would give away that the person is receiving treatment. Placebos may be used when testing whether a new treatment gives better results when it is being added to the standard treatment. One group of people will be given the standard treatment plus the new treatment and one group of people will be given the standard treatment plus a placebo.

If you decide to take part in a clinical trial the research team must explain whether it is randomised and if they are using a placebo. If the trial is a blind trial then you will not know which treatment you are getting. You could be getting the new treatment, the standard treatment or a placebo, depending on the design of the trial.

You can find out more about the four phases of clinical trials and clinical trial design by

contacting CancerHelp UK or Macmillan Cancer Support (see page 7).

A personal experience

‘Making the decision about going on a randomised trial, where I may not have got the treatment I was hoping for was hard. I talked it through with my wife and a lovely nurse at the hospital steered us through the decision. In the end I decided that I wanted to take the chance.’

Should I take part in a trial?

Clinical trials are an important and normal part of medicine and taking part is voluntary. But, if you are invited to take part in a trial, you have to decide whether it suits you. Each trial will be looking for people who fit a very specific set of criteria. For example, your PSA level may need to be within a certain range, or your cancer may need to be at a particular stage. Other factors may also be taken into account, such as how fit you are and if the trial is taking place in a centre you can easily get to.

Whether you decide to participate in a trial or not, you should receive the same standard of care.

Before making any decisions, it is important to find out as much as you can about a trial including its potential advantages and disadvantages.

A personal experience

‘Before I decided to consent to the trial I felt it was important to educate myself about it. I was aware that the research team wanted me to know the virtues of the trial, but I wanted to know about the drawbacks as well.’

Advantages

Each trial is different but generally taking part in a trial could mean that you:

- Might have access to newer and perhaps more effective treatments otherwise unavailable outside the trial.
- Have more regular check-ups, tests

and support from doctors and nurses than usual. Some people find this very reassuring.

- Help to improve future cancer treatment for others.
- Feel that you are doing something positive about your health and taking an active role in your treatment and recovery.

A personal experience

‘For me the benefits of being on the trial were that the oncologist had more time to talk me through what was happening. All the people in the trial unit were wonderful and I was able to have scans every three months to check my progress.’

Disadvantages

- The possible inconvenience of more frequent testing. Some people find this makes them more anxious about their cancer.
- You may not know in advance what side effects you may get from the treatment.
- If the trial is randomised you will not get a choice about which treatment you have.
- As with most treatments, there is the risk that the new treatment may not help you, even if it helps others.

A personal experience

‘I received a letter from my GP asking if I wanted to take part in a clinical trial to find out about diagnosing and treating prostate cancer. At the time, I was unaware that I actually had prostate cancer, and I decided that as I felt in good health I had nothing to lose by taking part. As a result of the trial I was diagnosed with early prostate cancer, so the main advantage is that I have been fast-tracked through the system. The main disadvantage is that I could have had five years without the anxiety of knowing I had an early prostate cancer.’

Some questions to ask your specialist team about clinical trials are listed further on in this fact sheet. The answers may help you decide whether or not taking part in a clinical trial is right for you.

What does taking part in a trial involve?

If you decide to take part in a trial the research team will give you the full details of what it will involve. There will be differences between trials, which depend on what the trial is investigating and what type of trial it is. Normally being in a trial will involve filling in forms or questionnaires, a physical examination before the trial (pre-trial screening), and then visiting a hospital to have tests or treatments. Sometimes this will take place over a number of years.

A personal experience

'The trial I was involved in meant I had to travel a long way for treatment. So I made sure I planned a route where I could get a seat on the train, in case I felt tired.'

Giving your consent

The research team have to obtain consent from you. This means signing a form to say that you understand what the trial involves and that you agree to take part. The team should explain the trial to you in detail and answer your questions. They should also give you time to think about the information before you agree to sign the consent form. You may like to discuss the information with your partner, family or GP before deciding. Before you sign the form you could ask yourself:

- Do you feel comfortable with the frequency and types of tests (such as blood tests or scans) that need to be done during the trial?
- Can you get to the hospital for the tests and treatment? Some people having cancer treatment find travelling long distances very tiring.
- Do you clearly understand the possible side effects and risks of having the treatment?

A personal experience

'The research team explained all the risks in great detail. At first this felt a bit like unnecessary information, but I was glad that they were thorough and told me everything.'

Pre-trial screening

Once you have given your consent you will normally have a physical examination to make sure that you are suitable for the trial. The research team will ask you about your medical and treatment history, and any symptoms. You may have blood tests, scans and other tests. This is to check the stage and grade of your prostate cancer and any other health conditions you may have. Depending on the trial it may be that men with other health conditions cannot take part.

Your rights when taking part in a trial

You can continue to think about whether the trial is still right for you as the trial progresses. You can leave a trial at any stage without giving a reason. If you can give a reason this may help the research team design better clinical trials in the future. Leaving a trial does not mean that you cannot have treatment for your cancer, nor does it mean that health professionals will treat you differently. You will still be given the current standard treatment for your stage of cancer.

Information about you and the clinical trial is confidential. Your personal information should be stored securely and a code may be used, so you cannot be identified by name. The research team will let you know how the information gathered during the trial will be used. Normally your GP will be told that you are taking part in a clinical trial. The research team will tell you what information they will give to your GP.

If other health professionals who are not working on the clinical trial give you any treatment or medicines, ask them to contact the research team to discuss whether these will affect the outcome of the trial. The research team should give you details of who you can contact with any questions.

Emotional support

Deciding whether to take part in a clinical trial can be difficult. You or those close to you may be worried about the risks involved. Or you may be worried about the number of medical tests.

You can get support from your friends, family, GP or other health professionals. You can also call our confidential Helpline on 0800 074 8383 to speak to a specialist nurse.

If you have access to the internet, you may also like to sign up to The Prostate Cancer Charity Online Community, where you can make contact with other men who have been on clinical trials and find out about their experiences. Visit www.prostate-cancer.org.uk to sign up.

Once the trial has finished

If you decide to get involved in a clinical trial, the research team should tell you what will happen with the results of the research. For example, whether they will be published in a medical journal and whether you can see them. You should not be identified in any report or publication without your permission.

Why does it take so long to get the results from trials?

You may hear about research into a new treatment for prostate cancer in the news, but it might be many years before it actually becomes part of standard medical care. Developing a new procedure or treatment can take a long time, but this will vary depending on the type of treatment, how many patients are needed on the trial and the aim of the trial. For example, if the aim of a trial is to control early prostate cancer for as long as possible, patients will have to be monitored over many years, sometimes up to ten years. But new treatments for advanced prostate cancer might aim to control the cancer for a few months, so the treatments may be available more quickly.

How do I find out about prostate cancer trials ?

If you would like to find out about current clinical trials for men with prostate cancer you can:

- Ask your specialist team if there are any local or national trials that may be suitable for you.
- Call our confidential Helpline on 0800 074 8383.
- Search online lists of trials, such as the CancerHelp UK clinical trials database at www.cancerhelp.org.uk/trials/

If you find a trial that you are interested in, take the details to show your specialist team. They can help you decide whether it is likely to be suitable for you.

What happens if something goes wrong when I am on the trial? Am I covered by insurance?

How much time will I need off work?

When will the results of the trial be available?

Where will the trial results be published?

What support can I get during and after the trial?

More information

The Prostate Cancer Charity

This fact sheet is part of the **Tool Kit**. Call our Helpline on 0800 074 8383 or visit our website at **www.prostate-cancer.org.uk** for more Tool Kit fact sheets, including an **A-Z of medical words**, which explains some of the words and phrases used in this sheet.

CancerHelp UK

www.cancerhelp.org.uk
Freephone 0808 800 4040
Part of Cancer Research UK, CancerHelp provides information about cancer, including information about clinical trials.

Health Talk Online

www.healthtalkonline.org
Lets you share in other people's experiences of health and illness. You can watch or listen to videos of interviews and read about people's experiences of clinical trials.

Macmillan Cancer Support

www.macmillan.org.uk
Freephone: 0808 808 00 00
9am-8pm, Mon-Fri
Practical, emotional and financial support for people with cancer, family and friends. Information about cancer, its treatment and living with cancer.

The Prostate Cancer Charity makes every effort to make sure that its services provide up-to-date, unbiased and accurate facts about prostate cancer. We hope that these will add to the medical advice you have had and will help you to make any decisions you may face. Please do continue to talk to your doctor if you are worried about any medical issues.

The Prostate Cancer Charity funds research into the causes of, and treatments for, prostate cancer. We also provide support and information to anyone concerned about prostate cancer. We rely on charitable donations to continue this work. If you would like to make a donation, please call us on 020 8222 7666.

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Tell us what you think

We hope you have found this information useful. If you have any comments or suggestions about any of our publications, you can email literature@prostate-cancer.org.uk or write to The Information Team at The Prostate Cancer Charity, 100 Cambridge Grove, London W6 0LE

References to sources of information used in the production of this fact sheet are available on our website.

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