

A guide to prostate cancer clinical trials



In this fact sheet:

- What is a clinical trial?
- Why are trials done?
- Who works on trials?
- What are the different types of prostate cancer trial?
- Should I take part in a trial?
- What does taking part in a trial involve?
- Why does it take so long to get the results from trials?
- How do I find out about prostate cancer trials?
- Questions to ask your doctor or nurse
- More information
- About us

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.

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.

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.

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, and
- 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.



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. In the end I decided to take the chance.

A personal experience

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 11).

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.



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.

A personal experience

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.



For me the benefits 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.

A personal experience

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.

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.

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?



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.

A personal experience

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 speak to our Specialist Nurses on our confidential helpline. If you have access to the internet, you may also like to sign up to Prostate Cancer UK's Online Community, where you can make contact with other men who have been on clinical trials and find out about their experiences. Visit prostatecanceruk.org 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.
-  Speak to our Specialist Nurses on our confidential helpline.
- 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.

Questions to ask your doctor or nurse



You may find it helpful to keep a note of any questions you have to take to your next appointment.

Do you know of any clinical trials for prostate cancer that I could go on?

Can you tell me the possible benefits and risks of taking part in the trial?

Will I definitely receive the new treatment or procedure?

What extra tests will I need to have if I go on the trial?

How long will the trial last?

Will I need to travel to another hospital?

Will my travel or other expenses be paid back to me?

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

What support can I get during and after the trial?

More information

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.

About us

Prostate Cancer UK fights to help more men survive prostate cancer and enjoy a better life.



This fact sheet is part of the Tool Kit. You can order more Tool Kit fact sheets, including an **A-Z of medical words**, which explains some of the words and phrases used in this fact sheet.

All of our publications are available to download and order from the website. You can also order printed copies by calling **0800 074 8383** or emailing literature@prostatecanceruk.org

At Prostate Cancer UK, we take great care to provide up-to-date, unbiased and accurate facts about prostate cancer. We hope these will add to the medical advice you have had and help you to make decisions. Our services are not intended to replace advice from your doctor.

References to sources of information used in the production of this fact sheet are available at prostatecanceruk.org

This publication was written and edited by:

Prostate Cancer UK's Information Team

It was reviewed by:

- Hashim Ahmed, MRC Clinical Fellow in Urology, University College Hospital, London
- Wendy Ansell, Macmillan Urology Nurse Specialist, St Bartholomew's Hospital, London
- Stacie March, Radiotherapy Clinical Researcher, Guy's and St Thomas' NHS Foundation Trust, London
- Matthew Sydes, Senior Scientist, MRC Clinical Trials Unit, London
- Linda Welsh, Prostate Specialist Radiographer & Clinical Research Radiographer, Torbay Hospital, Torbay
- Prostate Cancer Voices
- Prostate Cancer UK Specialist Nurses

Tell us what you think

If you have any comments about our publications, you can email:

literature@prostatecanceruk.org

or write to the Information Team at:

Prostate Cancer UK
100 Cambridge Grove
London W6 0LE



Speak to our Specialist Nurses

0800 074 8383*

prostatecanceruk.org

Donate today – help others like you

Did you find this information useful? Would you like to help others in your situation access the facts they need? Every year, 40,000 men face a prostate cancer diagnosis. To help us continue providing free information, you could make a donation of any amount. Please call us on **020 8222 7666**, visit **prostatecanceruk.org/donations** or text **PROSTATE** to **70004****

There are many other ways to support us. For more details please visit:
prostatecanceruk.org/get-involved

**You can donate up to £10 via SMS and we will receive 100% of your donation. Texts are charged at your standard rate. For full terms and conditions and more information, please visit prostatecanceruk.org/terms



Prostate Cancer UK London

Cambridge House
100 Cambridge Grove
London W6 0LE

info@prostatecanceruk.org
020 8222 7622

Glasgow

Unit F22-24 Festival Business Centre
150 Brand Street
Glasgow G51 1DH

scotland@prostatecanceruk.org
0141 314 0050



© Prostate Cancer UK May 2011
To be reviewed May 2013

The helpline is open Mon - Fri 10am - 4pm, Wed 7pm - 9pm

*Calls are recorded for training purposes only.

Confidentiality is maintained between callers and Prostate Cancer UK.

Prostate Cancer UK is a registered charity in England and Wales (1005541) and in Scotland (SC039332). Registered company number 2653887.