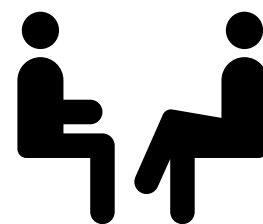


A guide to prostate cancer clinical trials



In this fact sheet:



- What is a clinical trial?
- Why are trials done?
- What are prostate cancer trials looking into?
- What happens in a clinical trial?
- Should I take part in a trial?
- What does taking part in a trial involve?
- How are trials approved and regulated?
- How can I find out about prostate cancer trials?
- Where can I get support?
- Questions to ask your medical team
- More information
- About us

This fact sheet is for anyone with prostate cancer who wants to find out more about taking part in a clinical trial – a type of medical research. Trials are done for all types of illnesses, but in this fact sheet we only look at clinical trials for prostate cancer. Your partner, family or friends might also find this information helpful.

Each hospital will do things slightly differently. Use this fact sheet as a general guide and ask your doctor or nurse for more information about clinical trials. You can also call our Specialist Nurses, in confidence, on 0800 074 8383 or chat to them online.

Symbols

These symbols appear in this fact sheet to guide you to more information:

-  Speak to our Specialist Nurses
-  Read our publications

What is a clinical trial?

A clinical trial is a type of medical research. It helps researchers and medical teams find new and improved ways of preventing, diagnosing, treating and managing health problems such as prostate cancer.

Clinical trials often test new medicines, medical procedures or medical equipment. They can look at many different things, including the following.

- **Prevention** – whether medicines, vitamins, diet, physical activity or certain lifestyles can affect a man's risk of prostate cancer.
- **Screening** – looking at which tests could be used as part of a screening programme (where lots of men would be tested) and whether this would be helpful or harmful for diagnosing prostate cancer.
- **Diagnosis** – trying out new tests, scans or other ways to help diagnose prostate cancer. For example, developing better tests to find out whether a man has prostate cancer or how quickly it might grow and spread outside the prostate.



- **Treatment** – testing new treatments or new ways of using existing treatments.
- **Lifestyle** – looking at whether lifestyle habits such as diet, physical activity or not smoking could help a man live longer, or affect how likely a man's cancer is to spread or come back after treatment.
- **Monitoring** – testing new tests or scans to help doctors monitor whether a treatment is working or how well a man's cancer is responding to treatment.
- **Quality of life** – looking at ways to improve the day-to-day life of men with prostate cancer. For example, looking at the side effects of treatment and ways to manage them.
- **Counselling and complementary therapies** – looking at other ways to help men and their loved ones deal with the effects of prostate cancer and its treatment.
- **Genetics** – looking at whether certain genes (or changes to genes) can affect a man's risk of getting prostate cancer, the growth of prostate cancer, or how well a man will respond to certain treatments. For example, some drugs may only work for men with a particular faulty gene.

Why are trials done?

Clinical trials aim to answer questions, usually about a treatment or a procedure. The following are common questions in trials testing a new test or treatment.

- Is it safe?
- Does it cause side effects?
- What is the best dose to use?
- Does it work?

- Does it work better than existing tests or treatments.
- How does it affect men's daily lives?

What are prostate cancer trials looking into?

Treatments for prostate cancer are an important area of research. There are trials looking at:

- newer treatments that only treat the areas of the prostate where there is cancer, such as focal cryotherapy, which uses extreme cold to destroy cancer cells
- developing and testing new treatments, such as immunotherapy (a treatment that uses the body's own immune system to destroy cancer cells) and PARP inhibitors (drugs that stop damaged cancer cells from repairing so that they die)
- whether treatments for advanced prostate cancer might also help men with earlier stages of prostate cancer
- whether treating the prostate itself (for example with radiotherapy or surgery) may be helpful for men with advanced prostate cancer
- whether the order in which treatments are given makes a difference
- ways to reduce the side effects of prostate cancer treatment
- how a man's genes might affect his response to treatment
- why a treatment that works for one man may not work so well for another.

For information on some of the prostate cancer trials that are happening in the UK at the moment, visit www.cancerresearchuk.org or speak to our Specialist Nurses.



What happens in a clinical trial?

Types of clinical trials

There are different ways of gathering evidence in cancer research. There are two main types of trials – observational studies and intervention studies.

In an **observational study**, researchers collect information about you that might tell them more about the risk of getting cancer, or the effects of cancer or its treatment. For example, they might select a large group of people and take blood samples, or ask them to answer questions about their lifestyle and diet at the start of the study. Then many years later, the researchers would look at whether or not those people developed cancer. They would then be able to see if there were any differences between the people who developed cancer and those who didn't.

In an **intervention study**, researchers give a group of people a treatment or test and follow them to see how well it works. One type of intervention study is called a randomised controlled trial – this is normally used to test new treatments (see below).

The different phases in clinical trials

Clinical trials that look at new treatments usually go through four different stages, called phases. If a phase is successful, the trial moves on to the next phase. Each phase helps researchers answer different questions and collect more information about the new treatment.

- **Phase 1** finds out about safety and side effects, and how the body responds to the new treatment. The research team will also begin to work out the best dose to use.
- **Phase 2** looks at how well a treatment works. It also collects more information about safety, side effects, and the best dose to use.
- **Phase 3** tests a new treatment, or a new way of using an existing treatment, against a placebo (see page 4) or the standard treatment, if there is one. And researchers continue to look at safety and side effects.
- **Phase 4** takes place after a new treatment is licensed and in use. Researchers collect information about long-term risks, side effects and benefits. They might also look at how well the treatment works in specific groups of people.

Phase 1 and 2 trials include small numbers of people and usually take place at specialist centres. Phase 3 and 4 trials usually involve many more people, sometimes thousands, and usually take place at your local hospital. Some trials may have an earlier stage called phase 0. This involves using a very small dose of a treatment to test how it behaves in the body.

Randomisation

A randomised trial is a way of testing a new treatment. Everyone taking part is put into different groups at random, usually decided by a computer. Neither you nor your medical team can choose which group you go in.

There are usually two groups in a randomised trial. One group has the new treatment. The other, called the control group, has the standard treatment or a placebo (see page 4). This is called a randomised controlled trial. The research team can then compare results from the two groups. Some trials have more than two groups (multi-arm trials). They allow researchers to test and compare several treatments at the same time.

One reason that trials are randomised is so that the research team can't choose who goes into which group based on what they know about their patients. This helps to prevent bias, which is when things such as the way a trial is carried out could affect the results of the trial. For example, researchers might put people who they thought were either healthier or more unwell into a particular group on purpose or without realising it, which could make the results of the trial unreliable.

Randomised trials are a good way of making sure people are put into groups fairly. This means that a randomised trial is more likely to produce reliable results than a trial that isn't randomised. Almost all phase 3 trials and some phase 2 trials are randomised.



Making the decision about going on a randomised trial, where I may not have got the treatment I was hoping for, was hard. In the end I decided to take the chance.

A personal experience

Placebo

A placebo is a dummy treatment. It can look or feel the same as the drug or procedure that's being tested. For example, it can be a pill that contains an inactive ingredient that won't have any effect, like sugar. People can sometimes feel better when they have a placebo because they think they are having a real treatment. This is known as the 'placebo effect'.

Comparing a group of people taking a new treatment with a group taking a placebo can show if the new treatment is really working. A drug that actually works will have a greater effect than the placebo.

A placebo is only usually used if there is no standard treatment, or if the new treatment is being given along with the standard treatment. Whether you decide to take part in a trial or not, you should receive the best care and support. Wherever there is a standard treatment or standard of care, new treatments are tested against this. So even if you don't get the new treatment, you will still have the best available treatment.

Blinded trials

In a blinded trial, you won't know whether you are getting the trial treatment, the standard treatment or a placebo. They will all look the same. Trials need to be 'blind' because just knowing what treatment you are getting can affect how you respond to it, and make the results unreliable.

Often the researchers who give you your treatment are also 'blinded'. This means they don't know which treatment you're getting either – so they can't be influenced by what they know. When both the patient and the researcher don't know which treatment is being used, this is called 'double blinding'. However, researchers can find out which treatment a person is having if there are any problems or concerns about your safety or the treatment itself.

Not all trials can be blinded. For a blinded trial to work, the treatments need to look similar and you shouldn't be able to work out or guess which treatment you are having.

If you decide to take part in a clinical trial, the research team must tell you whether it is randomised, if they are using a placebo, and if it's a blinded trial.

Safety

Before any trial begins, there is a long and thorough process to make sure it's as safe as possible. There are many stages of research before a drug is tested in people. And when it's ready to be tested in people, experts design the trial very carefully to make sure it's safe.

You'll have checks and tests before the trial starts (see page 7) to make sure you're suitable for the trial and it's safe for you to take part. Once the trial begins you'll be monitored closely so that any problems are spotted early and can be dealt with.

Clinical trials can't go ahead unless they have insurance, so you should be covered if there are any problems. Ask the research team for more details about what you are covered for.

For more information about how trials are run, visit www.cancerresearchuk.org

Should I take part in a trial?

Taking part in a clinical trial is a personal decision and the answer will not be the same for everyone. Without clinical trials and research studies we wouldn't have the treatments we have now.

Thousands of people volunteer every year to take part in trials. You may want to talk to your partner or family to help you decide. But you have to decide if it's right for you.

You should never feel like you have to take part. Your care will not be affected if you decide not to take part. And you should continue to receive the best care available, whatever you decide.



Before I decided to take part I wanted to learn all about it. I had an idea of some of the benefits of the trial, but I wanted to know the disadvantages too.

A personal experience

If you find a trial that could be suitable for you, find out as much as you can about it (see page 6). Each trial is different, but these are some of the possible advantages and disadvantages.

Advantages

- You might be able to have treatments that aren't available outside the trial.
- You may have more regular check-ups, tests and support from doctors and nurses than usual – some men find this very reassuring.
- You will be helping to improve future cancer treatment for others.
- You may feel you're doing something positive about your health and taking more control of your treatment and recovery.

Disadvantages

- There could be extra check-ups for many months or years afterwards, with questionnaires, tests or scans. Some men also find that having lots of tests makes them worry more about their cancer.
- As with all medicines, clinical trial drugs may have side effects. Talk to the research team about the possible side effects, and how common they are.
- You might not know about all the possible side effects before the trial starts. The research team might not know about them all yet.
- If the trial is randomised (see page 3) you won't be able to choose which treatment you have.
- If the trial is blinded (see page 4), you won't know which treatment you are getting.
- The new treatment may not be any better than the existing treatment.
- The new treatment might not help you, even if it helps others.
- Taking part may affect any insurance you already have and what insurance you can take out. For example, you may find it hard to be accepted for travel insurance.
- You may not be able to take part in the trial (see page 7), or you may have to leave the trial part way through. Some men say this can be very disappointing.

On page 10 we've suggested some questions to ask your medical team. The answers may help you decide if taking part in a trial is right for you.



For me, the benefits of being on the trial were that the oncologist had more time to talk me through what was happening, and I was able to have regular scans.

A personal experience

What does taking part in a trial involve?

There are differences between trials depending on the type of trial and what the trial is looking at. If you decide to take part in a trial, the research team should give you information about what it involves.

For each trial, researchers need to find people who fit very specific requirements. These are called inclusion and exclusion criteria. For example, they might need men with a certain PSA level, or men with cancer at a particular stage. They might also consider other things, such as how fit you are. This means that before the trial, you'll probably need to have checks and tests to see if you're suitable (see page 7).

During the trial you'll usually go to a hospital to have your treatment, as well as tests or scans. You'll have regular check-ups as part of the trial. You might have your usual hospital checks as well.

You won't be paid for taking part in a trial. Some trials may offer to pay for things like travel to and from the hospital. Ask your research team what they will pay for.



Taking part in a trial makes me feel that I'm giving something back for all the help I've received.

A personal experience



Other than the regular trips to the hospital for radiotherapy there was no problem with the treatment and staff were kind and friendly.

A personal experience

Getting information and giving your consent

Before you start on a clinical trial, the research team has to get your consent. This means signing a form to say that you understand what the trial involves and that you agree to take part.

Before you agree to take part, the research team should:

- explain the trial to you in detail
- give you written information about the research, called a participant information sheet
- talk you through everything
- answer your questions
- give you time to think before you decide whether to sign the consent form.

Make sure you find out everything you can about the trial so that you have all the information you need to make a decision that's right for you. And don't feel that you have to make a quick decision.

You might want to discuss the trial with someone else before you decide – maybe your partner, family, GP, hospital doctor or nurse. Or you can call our Specialist Nurses. They'll be happy to discuss the trial with you.



Before you sign the consent form, ask yourself these things.

- Am I comfortable with the tests that need to be done during the trial – and with how often they will happen?
- Can I get to the hospital easily for the tests and treatment? Some people having cancer treatment find travelling long distances very tiring.
- Do I clearly understand the possible side effects and risks of having the treatment, and that there might be unexpected side effects?
- If the trial is blinded, am I comfortable with not knowing which treatment I will receive?
- How might taking part affect my lifestyle or daily life?
- Will taking part affect any treatment I'm currently receiving or planning to have?

If you decide to go ahead, the research team should also tell you who to contact if you have any questions or concerns during the trial.



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

A personal experience



The trial I joined 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.

A personal experience

Checks and tests before the trial

Once you've given your consent, you'll have some tests and checks to make sure you're suitable for the trial. The research team will ask about your medical and treatment history, and any symptoms you have. You'll also have a physical examination and you might have blood tests, scans and other tests. This is to find out more about your prostate cancer and any other health problems you might have. In some trials, men with certain other health problems won't be able to take part.

If the tests show that you don't meet the criteria for the trial, you won't get to take part. But you will still get the best care available.

Can I leave the trial?

You can leave the trial at any time without giving a reason. But if you're happy to give a reason, it could help the research team to improve their trials in the future.

Leaving a trial will not affect any future care you receive, so you will still have treatment for your cancer. You'll be offered the standard treatments for your stage of cancer. Health professionals won't treat you differently because you've left a trial.

What will happen to my personal information?

Your personal information should be stored securely and kept confidential. The research team might use a code so you can't be identified by name. They should let you know how any information they collect during the trial will be used and ask for your permission to use your information.

Normally your GP will be told that you're taking part in a clinical trial. The research team should tell you what information they will give to your GP. If your GP, or other health professionals who aren't involved in the trial, prescribe you any treatment or medicines – not just for prostate cancer – ask them to contact the research team to make sure it won't affect the trial.

What happens when the trial finishes

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 if you can see them. You won't be identified in any report or publication without your permission.

If the trial is successful, you might want to keep having the treatment after it ends. This is sometimes possible, but not always. Ask the research team about this before the trial starts. If a new treatment works well, the research team might stop the trial early so that everyone on the trial can be offered it, not just those in the treatment group. They might also stop the trial early if the new treatment doesn't work well or causes too many side effects.

The research team may also want to stay in touch for some time after the trial. This is so that they can collect long-term information about the effects of the treatment you received.

Why can trials take so long?

Sometimes you might hear about a new treatment years before it actually becomes available. This information could come from results during the very early stages of the research, before the new treatment has been fully tested. So it may be a while before the new

treatment is available. How long depends on lots of things, such as the type of treatment, how many patients are needed on the trial and the aim of the trial.

How are trials approved and regulated?

All clinical trials must follow strict rules and guidelines to make sure the research is well planned, safe and fair (ethical) to anyone taking part. Before researchers in the UK can involve people in their research, their study must be approved by two main groups who make sure the research is carried out to a high standard. These are:

- **Medicines and Healthcare products Regulatory Agency (MHRA)**
This makes sure that any trials looking at new medicines or medical devices follow good clinical standards.
- **Research ethics committee (REC)**
This makes sure that everyone involved is protected from any harm and that your rights are looked after. It also checks that the study is ethical, and makes sure the risks aren't greater than the possible benefits.

Any research taking place in the NHS in England and Wales is approved by the Health Research Authority (HRA) and Health and Care Research Wales (HCRW). HRA and HCRW approval includes an REC review and checks that the study meets all the necessary rules and requirements.

Health and Social Care Research and Development (HSC R&D) organises permission for research in Northern Ireland. In Scotland, permission for research is organised by NHS Research Scotland.

Once a trial is approved, it is monitored to make sure the researchers continue to follow all the rules. The groups that approve the research can also stop any study if they are worried about its safety.

How can I find out about prostate cancer trials?

If you are thinking about joining a trial, speak to your doctor or nurse first. They can let you know about any local or national trials that may be suitable for you. You can also:

- search Cancer Research UK's list of clinical trials in the UK – this only shows some of the current trials
- search the Be Part of Research database at **www.bepartofresearch.nihr.ac.uk**
- speak to our Specialist Nurses for the most up-to-date information on clinical trials
- see a map of clinical trials funded by us at **prostatecanceruk.org/research/clinical-trials**



If you find a trial you're interested in, it's important to show the details to your doctor or nurse. They can help you decide if it's likely to be suitable for you.

Where can I get support?

Deciding whether to take part in a clinical trial can be difficult. You might want to ask questions or raise concerns before, during or after a trial. When a trial ends you might also feel you need some support.

Who can help?

Your medical team

It may be useful to speak to your nurse, doctor, GP or someone else in your medical team. They can explain your diagnosis, treatment and side effects, listen to your concerns, and put you in touch with others who can help.

Trained counsellors

Many hospitals have counsellors or psychologists who specialise in helping people with cancer – ask your doctor or nurse at the hospital to refer you. You can also get free counselling on the NHS, or you could see a private counsellor. To find out more, visit **www.nhs.uk/counselling** or contact the British Association for Counselling & Psychotherapy.

Local support groups

At local support groups, men get together to share their experiences of living with prostate cancer. Some groups have been set up by local health professionals, others by men themselves.

Prostate Cancer UK services

We have a range of services to help you deal with problems caused by prostate cancer or its treatments, including:

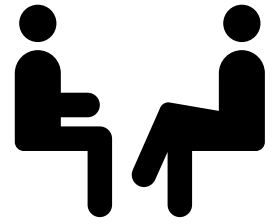


- **our Specialist Nurses**, who can help with any questions in confidence
- **our one-to-one support service**, where you can speak to someone who understands what you're going through
- **our online community**, a free forum to ask questions or share experiences
- **our fatigue support service**, delivered over the phone by our Specialist Nurses.

To find out more about any of our services, visit **prostatecanceruk.org/get-support** or call our Specialist Nurses on **0800 074 8383**.



Questions to ask your medical team



You might find it helpful to keep a note of any questions you have, to take to your next appointment. You and your family may have additional questions.

Are there any clinical trials for prostate cancer that I could take part in?

What will the trial aim to find out?

What are the possible benefits and risks of taking part in the trial, including any possible side effects?

What extra tests and appointments will I have if I take part in the trial?

Will I need to travel to another hospital? If so, will my travel or other expenses be paid?

What support can I get during and after the trial?

Who should I contact if I have questions while I'm on the trial?

Is it safe?

More information

Be Part of Research

www.bepartofresearch.nihr.ac.uk

Information about clinical trials in the UK. Includes a database of current clinical trials and information on how to contact the trial team.

British Association for Counselling & Psychotherapy

www.bacp.co.uk

Telephone: 01455 883 300

Information about counselling and details of therapists in your area.

Cancer Research UK

www.cancerresearchuk.org

Telephone: 0808 800 4040

Information about cancer, including a database of some clinical trials.

Healthtalk.org

www.healthtalk.org

Watch, listen to and read experiences of men with prostate cancer.

Macmillan Cancer Support

www.macmillan.org.uk

Telephone: 0808 808 0000

Practical, financial and emotional support for people with cancer, their family and friends. Includes information about clinical trials and lists websites where you can search for them.

NHS website

www.nhs.uk

Information about conditions, treatments and lifestyle. Includes a database of clinical trials.

UK Approval bodies

Information about how clinical trials are approved.

- **In England:** Health Research Authority
www.hra.nhs.uk
- **In Wales:** Health and Care Research Wales
www.healthandcareresearch.gov.wales
- **In Scotland:** NHS Research Scotland
www.nhsresearchscotland.org.uk

- **In Northern Ireland:** Health and Social Care R&D
www.research.hscni.net

About us

Prostate Cancer UK has a simple ambition: to stop men dying from prostate cancer – by driving improvements in prevention, diagnosis, treatment and support.



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

Download and order our fact sheets and booklets from our website at prostatecanceruk.org/publications or call us on **0800 074 8383**.

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 our Health Information team.

It was reviewed by:

- Johann de Bono, Consultant in Medical Oncology, The Royal Marsden NHS Foundation Trust
- Vincent Gnanapragasam, Consultant Urologist, Cambridge University Hospitals NHS Foundation Trust
- Nikola Hawkins, Consultant Cancer Practitioner, Gloucestershire Care Services NHS Trust
- Joe O'Sullivan, Professor of Radiation Oncology, Queen's University Belfast
- Our Specialist Nurses
- Our Volunteers.



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, over 47,000 men face a prostate cancer diagnosis. Thanks to our generous supporters, we offer information free to all who need it. If you would like to help us continue this service, please consider making a donation. Your gift could fund the following services:

- £10 could buy a Tool Kit – a set of fact sheets, tailored to the needs of each man with vital information on diagnosis, treatment and lifestyle.
- £25 could give a man diagnosed with a prostate problem unlimited time to talk over treatment options with one of our Specialist Nurses.

To make a donation of any amount, please call us on **0800 082 1616**, visit **prostatecanceruk.org/donate** 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



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t Follow us on Twitter: **@ProstateUK**

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To be reviewed May 2022

Call our Specialist Nurses from Monday to Friday 9am – 6pm, Wednesday 10am – 8pm

* Calls are recorded for training purposes only.
Confidentiality is maintained between callers and Prostate Cancer UK.

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