

Clinical trials for pancreatic cancer

This fact sheet is for anyone who would like to find out more about clinical trials for pancreatic cancer. They can be an important treatment option for people with pancreatic cancer. In this fact sheet we explain what clinical trials are, what they involve and how to find a clinical trial.

Each hospital and trial may do things slightly differently, so use this fact sheet as a general guide. If you have any questions, speak to your doctor, nurse or another member of your medical team.



You can also speak to our specialist nurses on our confidential Support Line. Call free on **0808 801 0707** or email **nurse@pancreaticcancer.org.uk**

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Key facts

- Clinical trials are medical research studies involving people.
- Most pancreatic cancer trials are looking at different treatment options.
- Clinical trials for pancreatic cancer are important because they show us what treatments and care do and don't work. They help to improve future pancreatic cancer treatments and medical knowledge.
- New treatments go through different types of trial, known as phases. Each phase involves more people.
- You may have access to new treatments through a clinical trial. But the new treatments may not be any better than the treatments that are already available.
- If you are interested in a trial, ask the doctor or nurse any questions you have. You can find some suggested questions on page 11.
- Each trial has strict rules for who can take part. Not all trials are suitable for everyone.
- If you decide to take part in a trial, you will be given detailed information about it, including information in writing.
- You can leave a clinical trial at any time, without it affecting your care.



Use our Clinical Trial Finder to search for clinical trials for pancreatic cancer in the UK, at:
pancreaticcancer.org.uk/clinicaltrials



You can speak to our specialist nurses on our confidential Support Line if you have any questions about clinical trials. Call free on **0808 801 0707** or email **nurse@pancreaticcancer.org.uk**

What are clinical trials?

Clinical trials are medical research studies involving people. They help researchers and doctors find out if a new treatment or a new way of providing care:

- is better than a current one
- has side effects
- helps people to feel better
- is safe.



We have videos about clinical trials and people's experiences of taking part in them. You can watch them on our website, at: **pancreaticcancer.org.uk/trialvideos**

Why are clinical trials important?

Clinical trials for pancreatic cancer are important because they show us what treatments and care do and don't work. They can also look at what may increase the risks of getting pancreatic cancer, how to prevent it and may find better ways to diagnose it.

Clinical trials for pancreatic cancer may include:

- finding ways to diagnose pancreatic cancer at an earlier stage
- finding better ways of giving existing treatments – for example, combining different chemotherapy drugs or giving drug combinations in different ways
- testing new treatments
- looking at ways to control the side effects of treatments
- looking at how best to provide care.

Most pancreatic cancer trials are looking at different treatment options. They aim to find better treatments that can help people live longer and improve the quality of their daily life.

Some trials also look at how people feel as a result of treatment, or what they think about the treatment they have had. The trial may call this patient reported outcome measures (PROMS) or patient reported experience measures (PREMS).

If you are interested in taking part in a clinical trial, ask your doctor or nurse if there are any trials that are suitable for you.

What types of clinical trials are there?

Before any new treatment for pancreatic cancer is tested on humans in a clinical trial, it is thoroughly tested in a laboratory.

All clinical trials must also be approved by an independent ethics committee and by government agencies. They check that the trial will be carried out in a safe way. There is more information about this on the NHS website.

The new treatments being tested must then pass through several different types of clinical trials, known as **phases**. Each phase involves more people.

Phase 1 trials

Phase 1 trials are the first stage in testing a new treatment on people. They usually involve a small number of people (around 10–30) who may have different types of cancer. The aim is to find out:

- the safe dose of a drug and how often it can be given
- what the side effects might be
- how well people's bodies cope with the drug
- signs that the drug may have an effect on the cancer.

Phase 1 trials usually take place at specialist cancer centres. This may mean you need to travel to another hospital if the trial is not available in your local hospital.

There may be a waiting list to join the trial. Your doctor or nurse will be able to advise you on this.

Phase 2 trials

If the results of a phase 1 trial are good, the treatment will move to a phase 2 trial. A phase 2 trial usually involves more people – there may be as many as 100 people taking part.

In a phase 2 trial, the research team already know which dose to use from the phase 1 trial results. They now want to learn more about how effective this treatment may be for specific types of cancer.

A Phase 2 trial will also look at:

- whether the new treatment works well enough to test it in an even bigger trial (a phase 3 trial – see below)
- more information about what dose to use
- how the treatment affects people's quality of life
- more about the side effects and how to manage them.

If the results of the phase 2 trial are good, the treatment may move into a larger phase 3 trial.

Phase 3 trials

Phase 3 trials compare new treatments with the best treatment currently available. They can do this by directly comparing a new treatment with an existing one, or by comparing different doses or different ways of giving the treatment.

A Phase 3 trial will also look at:

- how effective the treatment is
- any side effects
- the impact on a person's quality of life
- any other problems that could develop, to learn more about how to provide the treatment safely.

Most phase 3 trials are randomised controlled trials (see page 7) and usually involve many more people than phase 2 studies. Larger numbers of people are needed so that even small differences in results can be seen more easily, which means the results of the trial will be more reliable. Some phase 3 trials are blinded trials (see page 7).

A new treatment usually has to show better results than the standard treatment before it can be introduced as a treatment on the NHS. Sometimes, a treatment needs to be tested in several trials before it is introduced. But if the trial is big enough and the results are good, several trials may not be needed.

Randomised controlled trials (RCT)

Some phase 2 and phase 3 trials are randomised. This means that there are at least two different groups in the trial. The people taking part are put into the groups at random, by a computer. One group will have the new treatment and the other group will have a treatment to compare it with. This could be a different dose of the new treatment, a standard treatment for pancreatic cancer, or a placebo (see below).

Blinded trials

Randomised controlled trials are sometimes blinded. People taking part in a 'blinded trial' will not know whether they are getting the new treatment or the standard treatment (or a placebo). The research team may not know either. They will give the best level of medical care to everyone in the trial. If they need to, the trial doctors can always find out whether someone is having the new treatment or the placebo.

A placebo

Sometimes phase 2 trials compare a new treatment to a placebo. A placebo is a 'dummy' drug that looks the same as the new treatment but does not do anything.

A placebo may be used in clinical trials if there is no standard treatment to compare the new treatment with, or if the new treatment being tested is being added to a standard treatment.

The placebo effect

Even though a placebo doesn't actually treat the cancer, it can affect how some people feel. For example, they might feel better because they think they are getting a treatment for their cancer (even though they aren't). This is called the 'placebo effect'. The research team will consider the placebo effect when they look at the trial results.

Phase 4 trials

Phase 4 trials are usually carried out soon after new drugs have passed all the previous stages and have been licensed for use in the UK. Phase 4 trials aren't needed for every drug.

Phase 4 trials aim to find out as much as possible about how safe the drug is by monitoring very large numbers of people. They also look at how well the drug works, learn more about side effects and what the long term risks and benefits are for people taking part. Phase 4 trials can also provide more information on the cost of the new treatment.

Who can take part in a clinical trial?

Each trial has strict rules for who can take part. These are called 'inclusion and exclusion criteria'.

They can include:

- your age
- what type of cancer you have, how big it is and whether it has spread (the stage of the cancer)
- what previous treatments you have had
- your medical history, including any previous cancer
- other medical conditions
- your blood test results
- your general health – for example, how well you are feeling or how active you are.

Your doctor or research nurse will be able to explain whether a trial is suitable for you.

To check if you are eligible for a trial and meet the criteria, you may need to have screening tests. These may include blood tests, scans or other tests. The screening tests help to make sure it is safe for you to take part, and that the treatment will have the best chance of working for you.

There are advantages and disadvantages to taking part in a pancreatic cancer clinical trial. These may vary, depending on the trial.

If you are interested in trials

- Use our Clinical Trial Finder to find open trials for pancreatic cancer in the UK.
- Cancer Research UK and the National Institute for Health Research 'Be Part of Research' trial finder also have information about clinical trials in the UK.
- You can also find out about clinical trials at [ClinicalTrials.gov](https://clinicaltrials.gov)
- The Elizabeth Coteman Fund gives grants to people with pancreatic cancer who can't afford the costs of travelling to take part in a clinical trial.

If you find a trial you are interested in, talk to your doctor or nurse about whether it could be suitable for you.

If there is a trial that is suitable for you, think about the possible advantages and disadvantages and discuss these with your doctor or nurse. Have a look at our questions to ask your doctor or nurse on page 11. This will help you to decide if the trial is right for you.

Possible advantages

- You may have access to new treatments, which may only be available as part of a clinical trial.
- There may be fewer side effects compared to the standard treatment.
- You may have more regular tests, which some people find reassuring.
- You will be supported by a research nurse – who you can contact about your treatment and symptoms.
- You may help to improve future pancreatic cancer treatments and medical knowledge.

Possible disadvantages

- The new treatment may not be any better than your current treatment.
- There may be more side effects compared to the standard treatment.
- Trials may be carried out at a different hospital and involve travel, which can be tiring and take up a lot of time.
- You may have to go to hospital more often for tests and treatment, which can be inconvenient and tiring.
- You may not like not knowing whether you are taking a new drug, the standard treatment, or a placebo.

Find out as much as possible about the trial to help you to decide if you want to take part. You can leave a clinical trial at any time, without it affecting your care.

You should discuss the advantages and disadvantages of taking part in a clinical trial with your doctor or nurse.



You can also speak to our specialist nurses on our free Support Line.

Deciding to take part in a clinical trial

Your doctor or nurse may tell you about a trial for pancreatic cancer that might be suitable for you. Or you might find out about a trial yourself, for example through our Clinical Trial Finder. Talk it through with your consultant or nurse to find out if a trial is suitable for you and to help you decide whether to take part.

You will be given detailed information about the trial, including written information. Make sure you ask about anything you don't understand, so that you have all the information you need. It's important to know exactly what is involved before deciding whether to take part.

“ They make it very clear: anytime you want to stop, that's fine. Have a good look at it and ask lots of questions. You're part of the process – you can't just sit on the sidelines, you're totally part of that trial. But ultimately, you've got to decide if it's right for you.”



Questions to ask your doctor or nurse

You might want to write down any questions you have for your trial doctor or nurse, to take with you.

- Are there any clinical trials that are suitable for me?
- What does the trial involve?
- What tests or treatment will I have, and how often?
- How long will the trial last?
- What are the advantages and disadvantages for me?
- Are there any potential side effects?
- Who can I talk to if I have any questions about the trial?
- What support is available for me during the trial?
- What should I do if I feel unwell or have any concerns during the trial?
- Who should I call out of hours, if I need to?
- If the trial involves extra hospital visits, will my travel expenses be covered?
- Can I leave the trial at any time if I change my mind?
- How can I be referred for a trial that is not open at my hospital?
- If I take part in the trial, will it delay me starting my treatment?
- How can I find out about the results of the trial?
- What treatment will I receive if I choose not to take part in the trial?

What happens if I decide to take part in a trial?

If you are offered a suitable trial, the doctors and nurses in the research team will explain:

- the purpose of the trial
- the advantages and disadvantages
- what is involved
- that you can leave the trial at any time.

You will be given detailed written information about the trial. You will also be given the name of a research nurse who you can speak to about any questions you have. There will be plenty of time for you to ask the research team questions and talk to them about what's involved.

If you do decide to take part, you will be asked to sign a consent form saying that you understand what is involved and agree to take part in the trial. This is called giving 'informed consent'. You will be given as much time as you need to decide whether to take part in the trial.

Even after you sign the consent form, you can still leave the trial at any time. You will never have to carry on with a trial if you don't want to.

You will be given a phone number to contact at any time, such as if you feel unwell or are admitted to hospital for any reason.

Screening tests

To check that you can take part in a trial, you may need to have some tests, sometimes called screening tests.

Screening tests may include:

- blood and urine tests
- scans, which produce pictures of the inside of your body
- biopsies, which take tissue samples from your body
- other tests, such as tests on your heart or eyes, if there is a risk that the new treatment could affect them
- a pregnancy test.

It may take some time to do these tests and get all the results. Speak to the research team and your doctor about them and how long they take, so that you know exactly what is involved.

The screening tests may find something that means you don't meet the trial entry criteria after all. It can be very disappointing and frustrating if this happens.



If you would like to talk about this or anything else, you can contact our specialist nurses on the Support Line.

You will still be given the best treatment and care that is available outside the trial. Sometimes there may also be other trials you may be suitable for instead. Speak to your doctor or nurse about your treatment options.

Complaints about clinical trials

Once you have joined a clinical trial, you can make a complaint if you are concerned about how it is being run.

You should first complain directly to the research team that is running the trial. If you feel your complaint is more serious, or that it is not being handled properly, then you can go directly to the NHS Health Research Authority.

Other ways to get involved with clinical trials

You may decide not to take part in a trial yourself, or you may find that there are no trials suitable for you. But if you are interested in research, you can still get involved in giving feedback on trial plans or the direction of research. Our Research Involvement Network is a good place to start if you would like more information about this, at: pancreaticcancer.org.uk/about-rin

What happens with the results of clinical trials?

Medical researchers have a duty to publish their results. Sharing research findings can show what was learned from the trial and any improvements the treatments could make to people's treatment and care.

The results are usually presented at meetings and conferences for health professionals. They may also be published online and in medical journals. Details of the people taking part in a trial are not included in the results.

The information you will get about a trial usually explains what will happen to the results. Ask your doctor or nurse how you can find out about the results if you would like to know them.

In this section, when we talk about results, we are not talking about how the trial treatments may affect you. That will be different for everyone. You will have tests while you are on the trial, to check how well the treatment is working. Speak to your trial doctor or nurse if you would like to know more about what difference the treatment has made to your own health.

What happens after the trial finishes?

If a trial is successful and the new treatment works, it can still take a long time before it is used in the NHS.

If the treatment involves a new drug, it will need to be licensed for use in the UK. It will also need to be approved for use in the NHS. This is done by the following organisations:

- the National Institute for Health and Care Excellence (NICE) in England
- the Scottish Medicines Consortium (SMC) in Scotland
- the All Wales Medicines Strategy Group (AWMSG) in Wales
- the Department of Health (DOH) in Northern Ireland.

They will look at the results of all the studies involving the new treatment and decide whether it should be funded on the NHS. Their decision is partly based on whether the benefits of the treatment outweigh the financial costs of providing it.

More information and support

Pancreatic Cancer UK services

We are here for everyone affected by pancreatic cancer.

Our specialist nurses are here to talk now

If your world has been turned upside down by a pancreatic cancer diagnosis, we are here to talk now. We can answer your questions, recommend practical steps and provide the emotional support you and those close to you need, when you need it most.

Call free on **0808 801 0707** or email **nurse@pancreaticcancer.org.uk**

Expert information

Our free information covers everything about pancreatic cancer to help you understand your diagnosis, ask questions, make decisions and live as well as you can.

Go to: **pancreaticcancer.org.uk/information**

Download or order our free publications at:
pancreaticcancer.org.uk/publications or call **0808 801 0707**

Our online forum

The forum is a supportive online space where everyone affected by pancreatic cancer can be there for each other at any time.

Go to: **forum.pancreaticcancer.org.uk**

Living with Pancreatic Cancer Online Support Sessions

Our online support sessions are hosted by our specialist pancreatic cancer nurses and will give you the chance to connect with others who have also been diagnosed.

Go to: **pancreaticcancer.org.uk/supportsessions**

Real life stories

Read other people's experiences of pancreatic cancer to find out how they coped with their diagnosis and treatment and their tips on looking after themselves.

Go to: **pancreaticcancer.org.uk/stories**

Useful organisations

All Wales Medicines Strategy Group

awttc.nhs.wales

Approves new treatments for use in the NHS in Wales.

Cancer Research UK

www.cancerresearchuk.org

Helpline: 0808 800 4040 (Mon-Fri 8am-8pm; weekends 9am-5pm)

Information for anyone affected by cancer, and a trial finder with clinical trials in the UK.

ClinicalTrials.gov

Find clinical trials in the UK.

Department of Health, Northern Ireland

www.health-ni.gov.uk

Approves new treatments for use in Health and Social Care in Northern Ireland.

Elizabeth Coteman Fund

www.ecfund.org

Tel: 01223 782171

Grants for expenses to take part in a clinical trial, and grants for people with pancreatic cancer who are struggling financially, for equipment and respite. Support and friendship to those affected by pancreatic cancer.

Healthtalk.org

Personal experiences presented in written, audio and video formats, including people talking about pancreatic cancer.

Macmillan Cancer Support

www.macmillan.org.uk

Support Line: 0808 808 00 00 (Every day, 8am-8pm)

Provides practical, medical and financial support for anyone affected by cancer.

Maggie's Centres

www.maggies.org

Tel: 0300 123 1801

Centres around the UK and online offer free practical, emotional and social support for anyone affected by cancer.

National Institute for Health and Care Excellence (NICE)

www.nice.org.uk

NICE provide guidance, advice and information for health professionals. They have produced guidelines for the diagnosis and care of people with pancreatic cancer:

www.nice.org.uk/guidance/ng85

National Institute for Health Research

bepartofresearch.nihr.ac.uk

The NIHR 'Be Part of Research' trial finder has information about clinical trials in the UK.

NHS

www.nhs.uk

Information about health conditions, living well, care, and local services in England. It also has more information about taking part in clinical trials, and how they are regulated in the UK.

NHS 111 Wales

www.111.wales.nhs.uk

Health information in Wales, including local services.

NHS Health Research Authority

www.hra.nhs.uk

Email: complaints@hra.nhs.uk

Handles public complaints about clinical trials.

NHS inform

www.nhsinform.scot

Information about different health conditions and living well, and local services in Scotland.

nidirect

www.nidirect.gov.uk

Information about local services in Northern Ireland, including health services.

This fact sheet has been produced by the Support and Information Team at Pancreatic Cancer UK.

We make every effort to make sure that our services provide up-to-date, accurate information about pancreatic cancer. We hope this will add to the medical advice you have had, and help you make decisions about your treatment and care. This information should not replace advice from the medical team – please speak to your doctor, nurse or other members of your medical team about any questions.

Email us at **publications@pancreaticcancer.org.uk** for references to the sources of information used to write this fact sheet.

Give us your feedback

We hope you have found this information helpful. We are always keen to improve our information, so let us know if you have any comments or suggestions. Email us at **publications@pancreaticcancer.org.uk** or write to our Information Manager at the address below.

Pancreatic Cancer UK

Westminster Tower
3 Albert Embankment
London SE1 7SP

020 3535 7090
enquiries@pancreaticcancer.org.uk
pancreaticcancer.org.uk

© Pancreatic Cancer UK February 2022
Review date February 2025

Registered charity number 1112708 (England and Wales), and SC046392 (Scotland)