



Clinical Trials

What are they

Clinical trials are medical research studies that test new treatments and ways of preventing, diagnosing or screening for cancer. Trials are essential for developing better treatments and improving healthcare for everyone. Trials are the only reliable way to find out if a new treatment is safe, has side effects, works better than the current procedure and makes you feel better.

Are they safe

Rigorous processes, including review by an NHS Research Ethics Committee, are in place to protect the rights, dignity, safety and well-being of participants. Each trial is designed to keep risk to a minimum and those taking part are monitored carefully throughout. All the possible risks and benefits of taking part in a trial would be clearly explained to you and at any point you are able to withdraw and have your standard treatment for your type and stage of cancer.

What are the benefits

You may receive a treatment that is only available in a clinical trial. You may have more regular check-ups, blood tests, CT scans or other cancer tests than usual, which you may find reassuring. You will be helping doctors to improve cancer treatments for future patients.

What are the drawbacks

You may have to make more trips to the hospital for extra tests and check-ups, which may increase your worry. You may have to do some paperwork in recording your medication. You may have unexpected side effects.

Different types of trials

There are four *types* or *phases* of clinical trials. Each type aims to find out something different about the treatment or procedure.

Phase 1

Are the earliest and are often have the smallest number of patients taking part. They aim to find out the safe dose and what the side effects are. People entering phase 1 trials often have advanced cancer and have had all available standard treatment.

Phase 2

They aim to find out if the new treatment works better than existing treatments and also tell doctors more about the best dose to give, possible side effects and how to manage them.

Phase 3

Test a new treatment directly against the best available or standard treatment. They are much larger than Phase 1 & 2 trials and provide a lot of information about the treatment or procedure being developed prior to it possibly becoming licensed.

Phase 4

Are for treatments that are already licensed and aim to find out more about side effects and long-term risks and benefits.

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What are *randomised* trials

Many phase 3 trials are *randomised* this means the people taking part are randomly assigned to different treatment groups by a computer, neither you or your doctor can influence which group you are in. This ensures that each group has a similar mix of patients - different ages/states of health.

What are *controlled* trials

These are designed to compare different treatments. Most compare a new treatment with standard treatment. The *trial group* would receive the new and *control group* the standard. In situations where there is no standard treatment, the control group would be given a placebo.

What are *blind* trials

In a blind trial, the participants are not told which group they are in as this might influence how they felt or how they reported their symptoms. Some trials are *double blind* which means neither the participants or the doctors treating them know which arm of the trial they are on.

What happens when a trial ends

Those organising the trial should always ask everyone taking part if they want to know the results. This should be available to anyone who wants it. Sometimes, if a patient feels the treatment they have received during the trial has helped them, they may be able to continue with it after the trial ends. This can vary so you should ask before you agree to take part.

How you can join a trial

All trials have guidelines about who can take part. These are usually called *eligibility criteria* and ensure that the sort of people taking part may benefit and are not exposed to avoidable risks. Trials are often run in a number of different hospitals or health centres. Your consultant or Clinical Nurse Specialist should be able to advise what is available and either give you direct information or tell you where to find it.

More Information

Information from the NHS about clinical trials:
www.library.nhs.uk/trials

The National Cancer Research Institute website offers information and links to many other sites, all dealing with research.
www.cancertrials.org.uk

Information from MRC (Medical Research Centre) Clinical Trials Unit:
www.ctu.mrc.ac.uk/TrialInfo.asp

UK Clinical Trials Gateway:
www.controlled-trials.com/ukctr
Enter type of cancer in the 'search for' box.

Cancer Research UK website that helps you find a trial related to your particular cancer, by entering the 'type of cancer' and clicking *find*.
www.cancerhelp.org.uk/trials/trials/default/.asp
