

What is a Clinical Trial

An information leaflet for children aged

13 - 18



NATIONAL CHILDREN'S
RESEARCH CENTRE

What is this booklet about?

If you are being treated for an illness, you may be asked to take part in a type of research study called a 'Clinical Trial'. This booklet has been written to inform teenagers about clinical trials.

What is a clinical trial?

Clinical trials are studies designed to answer specific questions about health and illness and how well medicines and treatments work. These studies give important information about how good and safe these treatments are.

- In this booklet we use the term 'treatment' to mean different types of health care, such as:
- Medicines or drugs to treat pain, infection, blood pressure or other sicknesses.
- Vaccines to prevent infections. These include measles, mumps and rubella vaccines.
- Medical equipment such as plasters, dressings and blood sugar measuring devices.
- Different types of surgery and scans of the body (X-rays).
- Physical therapies. These include different types of exercises to build strength after a sports injury or to help with balance and movement problems.
- Psychological therapies or behavioural therapy: These are therapies designed to help how we think about problems we may have.
- Educational programmes: These are programmes designed to help children and teenagers understand their medical condition.

Why are clinical trials needed?

The only way to really know how well a treatment works in people is to carefully study the treatment in people. A new treatment may or may not be better than an existing one and a clinical trial is needed to find out. Clinical trials are important studies where doctors and researchers compare treatments. They carefully study the information they gather so they can find out if the treatments are effective, safe and how best to use them in children and teenagers.

We need to know how effective the treatments we use are, we do this by studying:

- How well specific treatments work in teenagers like you
- How safe the treatments are and by finding out if they have any side-effects

This is very important for everybody, but it is really important for teenagers because many treatments we use have only been studied in adults.



Teenagers often have different medical problems than adults, so the treatments may work differently. Also, teenagers may react differently to treatments and so could have different side-effects.

Trials are often used to test new treatments. They can also be used to look at new ways of combining or using existing treatments to see whether giving them in a different way will work better.

Where do clinical trials take place?

Trials can take place in hospitals, universities, doctors' offices or community clinics.

Who is in charge of an approved clinical trial?

The principal investigator is the person who has thought up and designed the trial. This person is a doctor or another healthcare professional that understands your disease or illness and is looking at ways to improve treatment.

Before any trial can start, it must first be approved by an ethics committee. An ethics committee is an independent group of doctors, nurses, researchers and non-medical people. They carefully examine a detailed description of the study to decide whether it is of good quality and fair to ask people to take part in it.

The Irish Medicines Board (IMB) has been given the job of looking after the safety of clinical trials involving medicines by the Irish government. They must also study a detailed description of each clinical trial and give their permission before a trial involving medicines can go ahead.

Researchers must send in regular reports to the ethics committee and to the IMB to ensure the safety of people in the study.

Strict rules are in place to protect the rights, safety, well-being and dignity of people taking part in clinical trials. All patients are monitored carefully throughout the trial and their safety and well-being is everyone's priority.

Why have I been asked to take part in a clinical trial?

You may be asked because you have a medical condition that the study is looking at.

Do I have to take part?

No!

It is up to you. You will be given information about the study to read and keep. If you decide to take part, you may be asked to sign a form saying that you agree to take part (an assent form). Your parents/guardians will also be asked to sign a form and give their consent to your taking part.

If you agree to take part and sign the form, you are free to change your mind and stop taking part at any time without giving a reason. If you decide not to take part, or stop taking part at any time during the course of the study, this will not affect the care you get in any way and no one will be upset with you.

Are there different types of clinical trials?

Yes.

Treatments are first developed in the science laboratory to see whether they may be helpful in preventing or treating a particular illness. They are then tested on animals to check their safety and to find out how they affect the body. If they look like they may be useful, and are likely to be safe, they will then be tested through different stages of clinical trials in people. Clinical trials are carried out in two stages – 'early stage' and a 'later stage'.

Early stage trials usually involve a small number of patients or healthy people. These early stage studies can be used to 'fine tune' the treatment before it is tested on a large group of people.

Later stage clinical trials usually involve large numbers of people and are usually called 'randomised trials'. Medical devices are tested in a similar way.

Why should I participate in a clinical trial?

The aim of a clinical trial is to improve treatment of patients. Though you may or may not benefit

from the study yourself, people who are treated in the future will benefit from knowing how effective and safe the treatment is. Discuss this with your family and friends as well as with your doctors, nurses, health professionals and the researchers.

What is consent and assent?

A researcher asks a parent or guardian to give their permission (consent) to allow their child to take part in a clinical trial. The researcher must first tell the patient and the parents the things that might happen with a clinical trial and answer any questions that the parents or child have.

Researchers will also explain the research to each teenager and ask them to take part: this is called assent. This means each teenager must show they understand and want to take part in the research study.

For more answers visit
clinicaltrials.ie



What is “informed consent”?

You cannot be entered into a trial without you and your parents or guardians signing forms saying that you agree to take part. Informed consent is learning the facts about a clinical trial before deciding to take part. If you agree and your parents/guardians agree, you confirm that you have been given the important facts about a trial; that you understand them and that you have decided to take part in the trial.

What are “inclusion criteria”?

Inclusion criteria are conditions that patients must meet to make sure that they are suitable to be asked to take part in the clinical trial. For example, one study will need children between certain ages to be included (between 13 and 18 years of age) and certain blood test results.

What are “exclusion criteria”?

Exclusion criteria are conditions that mean a patient is not suitable to take part in the clinical trial.

For example, another study will not need children of a certain age (children less than 13 years of age), or if they are already taking a different medicine or treatment.

What is a “placebo”?

A placebo is a treatment that does not contain any medicine but may still look like a medicine; it could be a capsule filled with water. Placebos are used because sometimes people may begin to feel more positive and feel better if they are getting a medicine. Doctors need to know if they are feeling better because the medicine is working or if it has something to do with feeling more positive in general. By comparing children and teenagers who used the placebo and those who used the medicine, we can tell whether any difference seen in the patient is because of the medicine, and not just because of the patient thinking that they are getting a medicine.

Will my information be confidential?

All the records of your trial information will be kept confidential in the same way as your gp or hospital records. The researchers cannot tell anyone that you are taking part in the trial without asking you first. Strict rules are in place to ensure that personal information is kept confidential.

What happens at the end of a trial?

At the end of a trial the results will be available to everyone who took part. Once the trial has finished, the results are often presented at research meetings and published in medical and scientific journals so other doctors, healthcare professionals and researchers in other locations and countries can use the information to help their patients.

Remember no information about any particular person that took part in the study (for example, their name or address) is presented at a meeting or printed in a journal.

How can I find out about clinical trials that are happening now? There are lists (registers) of different trials and some of these are set out in our website. If you would like to take part in a clinical trial but have not been asked, you should discuss it with your doctor, nurse or healthcare professional. You should also discuss it with your parents/guardians. They may know about a trial that would be suitable for you. There may not always be a trial which is suitable for you or the particular type of disease you have.



For more answers visit
clinicaltrials.ie

What questions should I ask about a clinical trial to find out more?

These are some of the questions you may like to ask before deciding whether to take part in a clinical trial.

- What is the aim of the trial and how will it help children and teenagers?

- What treatment will I get if I don't take part in the trial?

- How long is the trial expected to last and how long will I have to take part?

- How long will it be before the results of the trial are known?

- What will happen if I stop the trial treatment or leave the trial before it ends?

- How much of my time will I have to give?

- What extra tests or appointments will I have?



The Irish Platform for Patient Organizations, Science and Industry ensures patients in Ireland have prompt access to new and developing innovative therapies. It is a patient-led platform which brings together patient organisations', science, industry and where possible state agencies to build consensus on policy, legislation and regulation of the development of new medicines, products, devices and diagnostics for un-met medical needs in Ireland.

www.ipposi.ie



NATIONAL CHILDREN'S
RESEARCH CENTRE

The National Children's Research Centre (NCRC) is a charitable organisation and the largest paediatric research facility in the Republic of Ireland, and supports investigations into the cause, diagnosis, treatment and prevention of childhood illness and injury, through a series of research grants to principal investigators (senior doctors and scientists) and through an MD/PhD/MSc academic training programme, funded by the Children's Medical Research Foundation (CMRF).

www.nationalchildrensresearchcentre.ie

For more answers
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