

What is a Clinical Trial

An information leaflet for children aged

8-12



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 something called a clinical trial. This booklet has been written to explain to you and other children about clinical trials.

What is a clinical trial?

Clinical trials are studies to see how well medicines or treatments work when they are used to treat different types of illness and conditions. These studies give us important information about how well the medicine works and if there are any side-effects. Medicine can be tablets, liquids, creams or injections to treat eczema (dry-skin), asthma (wheeze), infections (colds and viruses) or other sicknesses.

We sometimes want to know how well medical devices such as plasters, dressings, thermometers or breathing masks work on children.

Why are clinical trials needed?

The only way to really tell how well medicines and treatments work is to study them carefully. We especially need to know how well they work in children your age.

Why do we need clinical trials in children?

Clinical trials are very important for everybody, but it is really important for children because many medicines and treatments that are given to children have only been studied in adults.

Doctors need to know:

- What are the best medicines to give children when they are sick
- If one medicine works better than another
- If there is a better way to give someone a medicine such as offering a tablet instead of an injection
- If using a different amount (dose) of the medicine works better

We need to know what medicines work in children and if they are safe.

Without clinical trials, we cannot know the best way to give medicines to children as:

- **Children often have different medical problems to adults**
- **Children's bodies are different to adults.** They have smaller lungs (used to breathe in and out), less muscle around their bones, faster heart beats and they are constantly growing!
- **These differences all have an effect on how medicines work**

We also need to know if there are any side-effects:

- Sometimes the medicines given to children to treat an illness may cause an unwanted effect, like a headache, a skin rash or a tummy upset; this is called a 'side-effect'. It is important for doctors to know if there are any side-effects if children are to use the medicine that the doctors are studying.

Where do clinical trials take place?

They usually take place in hospitals or in doctor's offices.

Who is in charge of a clinical trial?

This is the person who has thought up and designed the trial. This person is a doctor or another healthcare professional that understands the illness that they are studying and is looking at ways to improve the treatment.

Clinical trials are approved by many different people before they can start. Permission is needed from different groups of doctors, nurses, scientists and non-medical people who check each study very carefully before it can start. The Irish Government also monitors the safety of all medicines and clinical trials in Ireland.

There are very strict rules in place to protect the safety and well-being of adults and children taking part in clinical trials.

Why would I be asked to take part in a clinical trial?

You may be asked because you have a medical condition that the study is looking at such as: eczema (dry-skin), asthma (wheeze), diabetes (too much sugar in the blood), or other sicknesses.



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 the study was explained to you and that you agree to take part; this is called an assent form.

Your parents or guardians will also be asked to sign a form to give their permission for you to take part; this is called a consent form.

You can change your mind and stop taking part at any time without giving us a reason. This will not affect the care you get in any way and no one will be upset with you.

What is consent and assent?

A doctor asks a parent or guardian to give their permission to allow their child to be part of a clinical trial; this is called consent.

Asking the boy's or girl's permission is called assent. This means the boy or girl must show they understand and want to be in the research study.

The doctor must first tell the parents, and the boy or girl, all the possible things that can happen with a clinical trial and answer any questions that the parents or child have.

You cannot be entered into a trial without your permission and your parents/guardians signing a consent form saying that they have also given their permission.

Are there different types of clinical trials?

Yes. Clinical trials are carried out in two stages - an 'early stage' and a 'later stage'. Early stage trials usually involve a small number of patients or healthy people and focus on safety and the amount of the medicine to use. Later stage clinical trials usually involve large numbers of patients and look at the long-term benefits and risks of the treatment so that doctors can decide whether or how best to use it.

Why should I take part in a clinical trial?

The aim of a clinical trial is to learn new information about medicines and treatments which will be of benefit to other children.

Though you may or may not benefit from the study yourself, children who are treated in the future will benefit from knowing how best to use the medicine or treatment and how safe it is.

Who can take part in clinical trials?

To take part in a clinical trial, there are conditions that patients must meet to make sure that they are suitable to take part – for example, they may need to be a certain age or have certain blood test results.

There may be other reasons that mean a child is not suitable to take part; they may have other medical conditions.

These rules are called 'inclusion' and 'exclusion' criteria.

Will anyone know that I took part in a clinical trial?

No one outside of the hospital will know that you took part in the study. All the health records will be kept confidential in the same way as your GP or hospital records. The doctors cannot tell anyone that you are taking part in the clinical trial without asking you first.

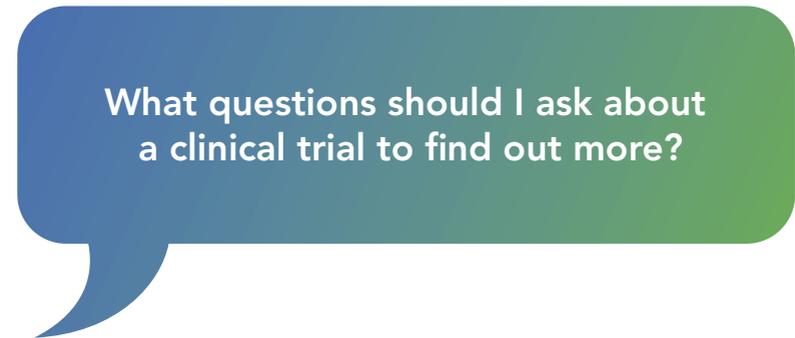
What happens at the end of a clinical trial?

The information collected on all patients is studied and the results are discussed at research meetings and printed in medical and scientific journals (publications) so that doctors and scientists in other locations and countries can use the

information to help their patients. 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?

If you would like to take part in a clinical trial but have not been asked, you should discuss it with your doctor or nurse. You should also discuss it with your parents or guardians. Remember that there may not be a trial which is suitable for you



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

- What is the reason for the trial and how will it help other children?

- 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?

- What will happen to me if I take part?

- What will happen if I stop the trial medicine 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?

- Will I need to take time off school?

- Will I need extra help from family and friends?

- Will I have to fill in questionnaires or keep a diary?

- What are the possible side-effects of the medicine?





The Irish Platform for Patient Organisations, Science and Industry (IPPOSI) ensures patients in Ireland have prompt access to new and developing innovative therapies. IPPOSI 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 unmet 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 Ireland. It 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. The NCRC is funded by the Children's Medical Research Foundation (CMRF).

www.nationalchildrensresearchcentre.ie

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