What is a clinical trial?

Information for potential or new trial participants to assist in making an informed decision.

Aotearoa Clinical Trials

Contents

What is a clinical trial?

A clinical trial is medical research involving people.

Before a new medicine can be approved by government regulators for testing in humans, it undergoes strict scientific testing to make sure its safety and effectiveness is known. All trials in humans must be reviewed and approved by an Independent Ethics Committee (IEC) before they begin to make sure that possible risks to patients are minimised.

There are two main categories of clinical trials:

- Interventional clinical trials

Interventional clinical trials are research studies that test a new medical, surgical, or behavioural intervention in people.

They are the primary way that researchers find out if a treatment, like a new drug, diet or medical device such as a pacemaker is safe and effective in people. Often a clinical trial is used to learn if a new treatment is more effective and/or has less harmful side effects than the standard treatment.

- Non-interventional clinical trials

Non-interventional/Observational trials observe people in normal settings.

Researchers gather information, group volunteers according to broad characteristics, and compare changes over time. For example, researchers may collect data through medical examinations, blood tests, or questionnaires about a group of older adults over time to learn more about the effects of different lifestyles on mental health.

What are the four phases of clinical trials?

Clinical trials advance through four phases to test a treatment, find the appropriate dosage, and look for side effects.

If, after the first three phases, researchers find a drug or other intervention to be safe and effective, the government regulator (FDA or Medsafe) may approve it for clinical use and continues to monitor its effects.

I **A Phase I trial** tests an experimental treatment on a small group of often healthy people (20 to 80) to determine a drug or device's safety and side effects.

II **A Phase II trial** involves more people (100 to 300) and the aim is to assess the effectiveness of the drug or device and whether the drug works in people who have a certain disease or condition. These trials also study safety, including short-term side effects. This phase can last several years.

III **A Phase III trial** involves up to 3000 people and aims to gather more information about safety and effectiveness of the drug or device. This is done by comparing it to other drugs or devices that treat a particular condition, studying the drug in different populations, trying different dosages and using the drug in combination with other drugs or devices.

IV **A Phase IV trial** takes place after the new drug or device has been approved by regulators for use in humans. A device or drug's effectiveness and safety are monitored in large, diverse populations. Sometimes, the side effects of a drug or device may not become clear until more people have taken it over a longer period of time.

Why participate in a clinical trial?

There are many reasons why people choose to join a clinical trial. Some join a trial because the treatments they have previously tried for their health problem did not work. Others participate because there are no other treatment options. Others take part because they want to help future generations by being part of the development of new medicines through clinical trials.

By being part of a clinical trial, participants may find out about new treatments before they are widely available. Additionally, some treatments are not funded by government programs and so the only way they are available is through a clinical trial.

People say that participating in a clinical trial is a way to play a more active role in their own health care as they develop a greater understanding of their own disease or condition. Other people say they want to help researchers learn more about certain health problems. Whatever the motivation, when you choose to participate in a clinical trial you become a partner in scientific discovery. Your contribution can help future generations lead healthier lives through the development of new and improved medicines.

Major medical breakthroughs could not happen without the generosity of clinical trial participants - such as yourself.

Liver function being assessed with a state-of-the-art Fibroscan machine

A spirometry machine is used to measure lung capacity

Where can I find a clinical trial?

There are many ways you can get help to find a clinical trial. You can talk to your doctor or other healthcare provider. Or, you can search on our website under recruiting trials.

www.aotearoatrials.nz

Support groups and websites that focus on a particular condition sometimes have lists of clinical trials. You may see ads for trials in your area on social media such as Facebook, the newspaper or on TV. Sometimes you may be invited by your hospital specialist, general practitioner (GP) or family/whaanau.

What is the next step after I find a clinical trial?

Once you find a trial you might want to be a part of, you will need to contact the clinical trial coordinator. The clinical trial coordinator will talk to you about the trial and if you are interested they will send you an information sheet to read. Then if you are still interested, they will make a screening appointment for you to come to the clinic and see if you qualify to participate. You can ask any questions you have relating to the clinical trial during the screening appointment.

Let your doctor know that you are thinking about joining a clinical trial. They may want to talk to the research team about your health to make sure the trial is safe for you and to coordinate your care while you are in the trial.

Scan to see our current recruiting trials

www.aotearoatrials.nz/recruiting-trials

Here's what happens in a clinical trial:

- Trial staff (e.g. study coordinator, nurse and doctor) explain the trial in detail and gather more information about you.
- Once you have had all your questions answered and agree to participate, you sign an informed consent form. This process is called Informed Consent.
- You are screened to make sure you are eligible to participate in the trial. The screening procedures may include physical examinations and blood tests.
- If accepted into the trial, you are given an appointment for a baseline visit. The researchers may do a series of tests during this visit, as described in your information sheet and consent form.
- You will be assigned to a treatment group as described in your information sheet and consent form.
- You will be asked to visit the research site at regularly scheduled times for trial related evaluations and so that the research team can collect information about effects of the intervention and your safety and well-being.
- All the trial related procedures and visits (e.g. parking and travel) included in a trial are free of charge.

You continue to see your regular doctor for usual health care throughout the trial.

What does ‘informed consent’ mean ?

Informed consent is the process of ensuring that participants in a clinical trial understand the risks and benefits of being involved in a particular trial. It is the responsibility of the clinical trial staff (usually the doctor, nurse, or study coordinator) to ensure that the participant understands their role, as a “participant of research” and not as a patient.

Informed consent involves the trial being explained in detail by the supervising doctor. Participants are then given printed material about the trial to take away and discuss with their family/whaanau or family doctor so that the participant can make the best decision for themselves as to whether to take part in a clinical trial or not.

Informed consent also explains what a participant’s responsibilities are should they agree to take part in a clinical trial.

How does the clinical trial team decide who will participate?

After you consent, you will be screened by trial staff to see if you meet the criteria to participate in the trial or if anything would exclude you. Screening may involve both mental and physical tests.

Your age, stage of disease, sex, genetic profile, family history, your specific health problems or medications and whether or not you have a support person (if required) who can accompany you to future visits may all be considered to see if you can take part in a particular trial.

Many volunteers must be screened to find enough people for a trial. Generally, you can participate in only one trial at a time.

Different trials have different criteria, so being excluded from one trial does not necessarily exclude you from another.

What are the benefits of participating in a clinical trial?

- Improved access to specialist doctors, procedures and medicines.
- Close attention paid to your condition, including timely reviews and follow up by experienced clinical trial doctors, nurses, and coordinators.
- Access to approved medications that may be helpful to your condition, but are not yet available in New Zealand.
- Learn about your condition and how you can manage or adapt your lifestyle to help your condition.
- Helping others by being part of research that assesses new and improved medicines for your condition.
- Our clinical trials unit is dedicated to clinical research and our staff are highly experienced.

What are the risks of participating in a clinical trial?

- You could experience unknown or unexpected side effects. For this reason, you will be given the trial doctors, nurses, and/or coordinators contact details so you can let them know if you experience any side effects.
- There may be no benefit from participating in the trial.
- The experimental treatment may not be as effective as existing treatment.
- You are not able to choose which treatment you are on so you could receive placebo (not the study drug or intervention) but the care you receive will still be according to local guidelines.

Adapted from the National Institute of Health USA

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More information is available
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www.aotearoatrials.nz

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