



Waikato District Health Board



Clinical trials patient information

Cancer and Blood Research Trials
Waikato Hospital



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Tēnā koutou katoa, haere mai, nau mai ki tēnei pānui he rauemi mau ki ou whānau mo ngā whakamatautau mate pukupuku, he pānui ki te awhina ki a koe mo tēnei kaupapa.

Greetings and welcome. This booklet is a resource for you and your family to better understand the procedures and tests involved with clinical trial cancer treatment.

Introduction

The objective of this booklet is to provide information for you and your whānau/family, to help improve your understanding of clinical trials and decide what is right for you before consenting to participate in a clinical trial.

Acknowledgements

Cancer and Blood Research Trials acknowledge the Blood and Leukaemia Foundation for granting permission to use material as a template within this booklet.

We also acknowledge the patients and staff at Waikato Hospital, who contributed towards producing this booklet.

Glossary

Arm/cohort/treatment group	A group of participants in a trial, who receive specific treatment according to the protocol.
Active comparator	A treatment considered to be as effective as the experimental medication.
Biopsy	The removal of a sample of body tissue for examination under a microscope to check for cancer cells or other abnormalities.
Clinical trial	A study in which you are assigned to a group to receive one or more treatments, sometimes no treatment, or a placebo.
Control arms	Treatment groups that receive either, another treatment used for the same condition (active comparator), or a placebo.
Double blinded trial	A participant along with the doctors, data collectors (etc.) are unaware of the treatment assigned to a trial participant.
Efficacy	The maximum ability of a drug or treatment to produce a result regardless of the dosage.
Eligibility criteria	Guidelines that need to be met to be able to participate in a clinical trial.
Enrolment	Being entered into a clinical trial once you have met the eligibility or inclusion criteria.
Experimental arm	A group which receives a new treatment that is being studied.
Experimental treatment	A new treatment that has not yet been approved by regulatory authorities such as Medsafe in New Zealand and the Food and Drug Administration (FDA) in America.
Informed consent	Being informed of the risks and benefits of participating in a clinical trial, so that you can decide if it is right for you.
Investigational agent	The study medication being tested.
Investigator	A doctor (oncologist/haematologist) involved in a clinical trial.
Monitor	A person contracted by the Sponsor to check that the information being collected about clinical trial participants is true and correct.

Participant information sheet	Written information about a clinical trial that includes a consent form for you and your doctor to sign if you decide to participate.
Placebo	An inactive (dummy) medication that looks the same as the investigational agent.
Phases	Clinical trials are divided into different stages, called phases. An early phase trial looks at whether a drug is safe and any side effects it may cause. A later phase trial aims to test whether a new treatment is better than existing treatments.
Principal investigator	The oncologist/haematologist who has overall responsibility for the trial at a particular hospital.
Protocol	A written description of how a clinical trial is to be conducted in a safe and consistent way.
Randomisation	Being assigned to one of the treatment groups (arms) of a clinical trial.
Randomised trial	A clinical trial in which groups of patients receive different treatments for the same disease, in order to compare them.
Recruitment status	Whether a clinical trial is open or closed to accepting participants.
Screening	The period between signing consent and being enrolled on a clinical trial. Tests such as blood tests and scans may need to be done during this time to check if you meet the eligibility criteria of the trial.
Single blinded trial	The participant is unaware of what treatment they are receiving.
Sponsor	The organisation that oversees the running of a clinical trial.
Treatment	A medication, therapy or medical device that is used in a clinical trial. It may be the investigational agent, the current treatment used for the condition or disease being studied, or a combination of these.

What is a clinical trial?

A clinical trial is medical research to find out the effect and safety of a new medical treatment or a new combination of treatments, to improve health outcomes for people with a particular disease. Some trials compare the effect of the best treatment available with a placebo or control, another treatment, or no treatment at all. A placebo is an inactive medicine or procedure. The results of clinical trials we offer today will provide improved treatment for patients in the future.

Clinical trial team

Many people are part of the clinical trial team, for example, nurse coordinators, data managers, doctors, radiologists, pharmacists, laboratory staff, all of whom are trained to provide trial specific care.

Privacy of patient information

The clinical trials team will keep your information private and confidential. You will be identified by a unique trial code on any information that is sent to the sponsor.

Why enter a clinical trial?

People enter trials in the hope that the treatment they are offered will be of benefit to them, or to access treatments that are not currently available in New Zealand.

Is it safe to take part?

Clinical trials are based on sound scientific knowledge and are governed by strict regulations. In New Zealand clinical trials are approved by an independent health ethics committee, which includes health professionals, scientists and members of the public. The Te Puna Oranga (Māori Health) team also review clinical trials.

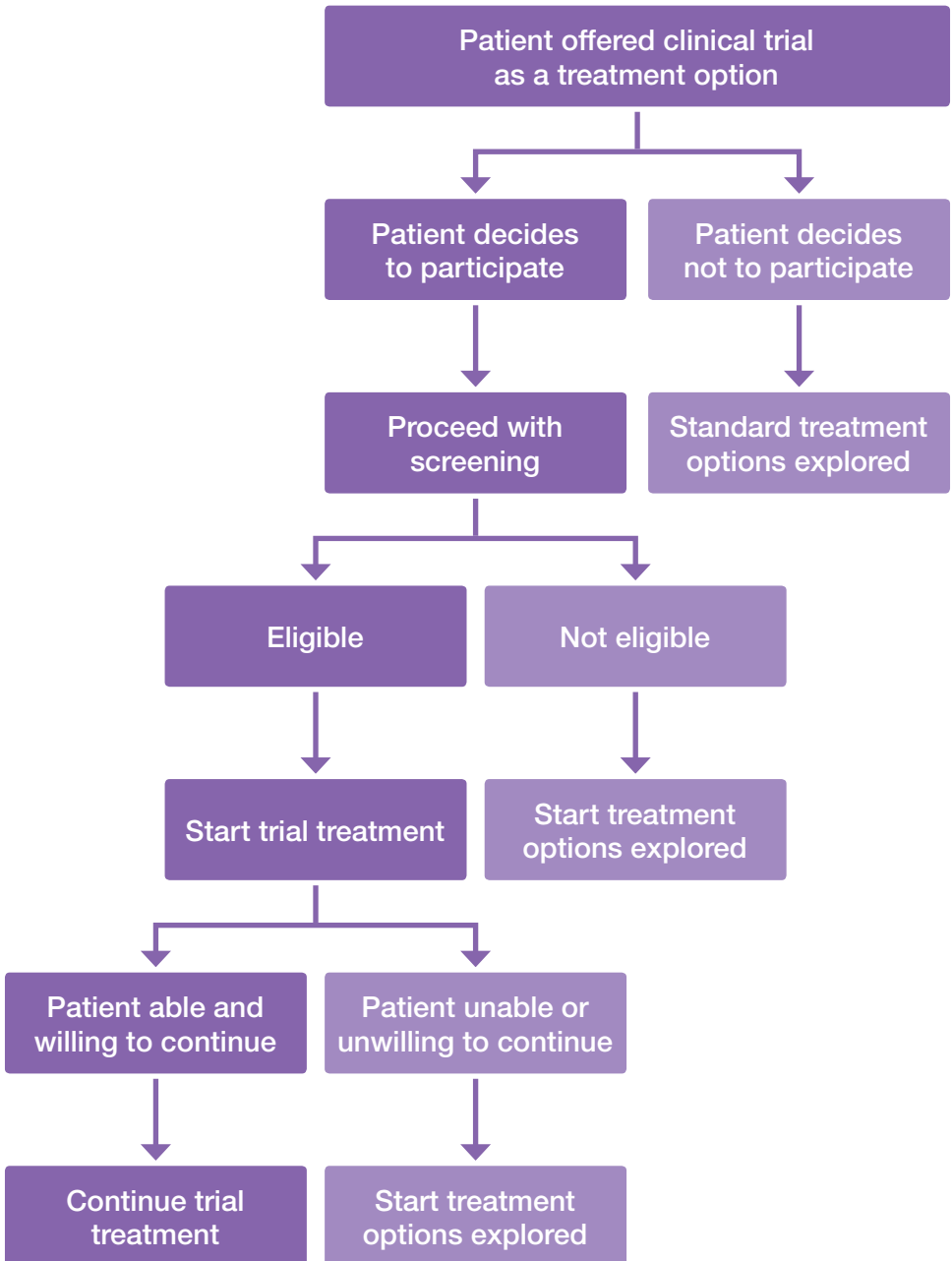
Informed consent

You have the right to be fully informed about the clinical trial before you make a decision to be part of it. Your agreement to participate is needed before any treatment can begin. This is known as “informed consent”.

If a clinical trial is an option for you, your doctor will give you a patient information sheet to take home and read carefully. It provides information about the trial, treatment/s, potential benefits and side effects, types of procedures to expect, number of visits, as well as the names of people to contact for further information or any concerns. You are encouraged to involve your whānau/family and GP in this process and to ask your specialist as many questions as you need to understand the trial. Be sure you are comfortable with your decision and never feel you are put under pressure by your doctor or family to join a trial – it is totally your choice. Once you understand what the trial involves and you are happy to participate, you and your specialist doctor can go ahead and sign the “consent form” together.

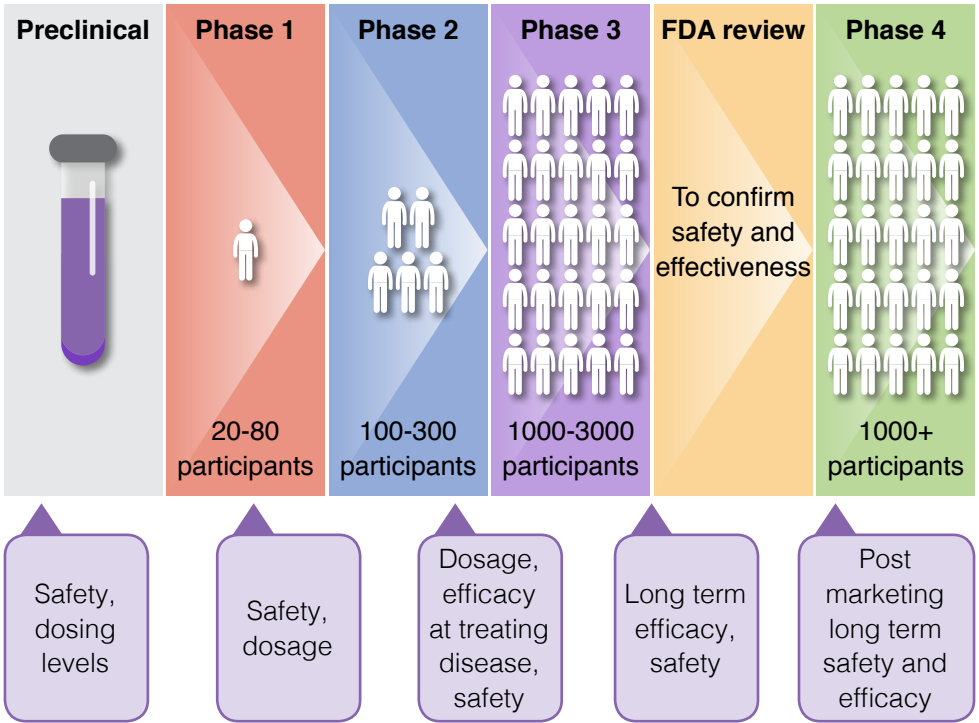
Standard process involved with a clinical trial

The following graph outlines the basic process involved with participation in a clinical trial; from the initial offer through to variations of treatment.



Phases of clinical trials

The clinical trial you are being offered to participate in will be at one of the phases of development in the diagram below.



Questions you may want to ask your specialist

- What is the difference between the trial treatment and the current treatment?
 - Is it more effective than the current treatment?
 - Will I have to come in more frequently?
 - Will I have more side effects than with the current treatment?
 - Will I have more tests done?
- How long is the treatment?
- What if I get placebo? Will my treatment be less effective than the standard one?



What to expect when participating in a clinical trial

Clinic visits

The screening visit will involve signing a consent form and having trial specific tests such as blood collection. The clinic visits will differ depending on the clinical trial you are offered. The trial nurse will check your weight, blood pressure, temperature and heart rate.

A thorough medical history will be taken and you will be asked about any current medications (including herbal supplements) that you may be taking. You are encouraged to bring a support person/s to the visits and ask questions.

Procedures

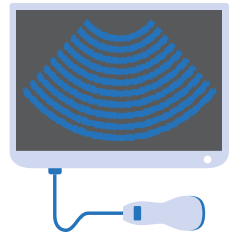
Procedures are tests done as part of screening for the trials and may continue to be done at set time points if a clinical trial is an option for you. These tests may include an ECG (Electrocardiogram, a test to record the electrical activity of your heart), Echo (Echocardiogram, a type of ultrasound scan to examine your heart), eye tests and various scans and or x-rays. Some of the tests will be performed at facilities that are not within the hospital.

Follow-up clinic visits

Follow-up visits may occur when you stop receiving the trial medications. These visits are necessary to enable the trial team to monitor your health.

What are my responsibilities?

- At each visit you will be asked to tell the trials team about any side effects which you may be experiencing as well as medication that you are taking. You may be asked to complete a daily diary with this information.
- You will be required to attend clinic visits more frequently so your doctor can closely monitor your health.
- An “Alert Card” will be given to you once you are enrolled in the trial, and this needs to be carried with you at all times. If you see any other health professional or are seen in any Emergency Department, please show them this card.



Sample collection

Blood, urine or other tissue samples may be required before entering the clinical trial, during and after treatment. A tissue sample is any material from your body. You may have already had a biopsy or tissue collection that can be used for the trial, but some trials require another biopsy. Your samples may be processed in a laboratory outside of New Zealand.



You may wish to consult your whānau or hapu-group about your samples being sent overseas, as some iwi may have strong beliefs involving the collective ownership of tissue samples. At Waikato Hospital, Te Puna Oranga (Māori Health) is consulted about specimen collection for every clinical trial.

Future research

Sometimes the researchers running a trial will ask if they can use your tissue samples for future research. More information can be provided if you consent to the trial.

Cancer research is ongoing and it is not possible to know what tests may be conducted in the future. Testing of your samples could help to understand the cause of certain conditions and develop new treatments. Although you will not benefit from this research you will contribute to improvements in future cancer treatment.



Your DNA (the chemical structure carrying your genetic information) may be tested to understand how certain conditions develop and how they can be treated.

In many trials, allowing your sample to be used for future research is usually optional and your decision does not affect your participation in the main trial.

Support and information services

Waikato

Cancer and Blood Research Trials, Waikato Hospital

Ph: 07 839 8976

Oncology, Waikato Hospital

Ph: 07 839 8604

Haematology, Waikato Hospital

Ph: 07 839 8899 (ask for the Haematology Clinic or Ward M5)

- Nurse lead lymphoedema clinic
- Psychosocial services
- Dietician
- Tu Haumaha (Oncology Kaitiaki)

Waikato District Health Board cancer services

Website: waikatodhb.health.nz/cancer-services

Waikato District Health Board – general information

Website: waikatodhb.health.nz

Te Puna Oranga (Māori Health), Waikato Hospital

Ph. 07 839 7628

- The Kaitiaki frontline service offers cultural support for Māori and their whānau – ask your nurse if you would like Kaitiaki support



Nationwide and further support

Breast Cancer Foundation

Ph: 0800 902 732 / 0800 BC NURSE

Website: www.breastcancerfoundation.org.nz/breast-cancer

Cancer Society

Ph: 0800 CANCER/0800 226 237 (Cancer information helpline)

Email: info@cancersoc.org.nz Website: www.cancernz.org.nz

Canteen

Supporting young people living with cancer

Ph: 0800 CANTEEN

Email: info@canteen.org.nz

Website: www.canteen.org.nz

Clinicaltrials.gov

A database of clinical trials conducted around the world

Website: www.clinicaltrials.gov

eviQ

Information for people having cancer treatment and their carers, whānau/family and friends

Website: www.eviq.org.au/patients-and-carers

HeadNeck NZ

Head and neck cancer support network

Website: www.headneck.org.nz

Health and Disability Advocate

An independent person you can talk to if you have a concern or complaint

Ph: 0800 555 050

Hospice Waikato

Specialist palliative care services

Ph: 07 859 1260 / 0800 HOSPICE

Website: www.hospicewaikato.org.nz

Leukaemia and Blood Cancer New Zealand

Ph: 0800 15 10 15

Email: info@leukaemia.org.nz

Website: www.leukaemia.org.nz

Look Good Feel Better

Facing cancer with confidence

Ph: 0800 865 432

Email: info@lgfb.co.nz

Website: www.lgfb.co.nz

Melanoma New Zealand

Ph: 0800 463 526

Website: www.melanoma.org.nz

Email: info@melanoma.org.nz / education@melanoma.org.nz

National Travel Assistance Scheme

Website: health.govt.nz/our-work/hospitals-and-specialist-care/national-travel-assistance-scheme

Pinc and Steel

Cancer Rehabilitation Trust

Website: www.pincandsteel.com

Rainbow Place

Hospice services for children and young people

Ph: 07 859 3848

Email: rainbowplace@hospicewaikato.org.nz

Website: www.rainbowplace.co.nz

Sweet Louise

Support for incurable breast cancer

Ph: 0800 11 22 77

Email: info@sweetlouise.co.nz

Website: www.sweetlouise.co.nz

Time Out

For those with life-threatening illness to spend quality time with friends and family

Ph: 09 214 5708

Website: www.timeoutnz.org

Whole Lotta Life Foundation

Cancer under 45

Website: www.wholelottalife.org

Frequently asked questions

What happens if I decide to change my mind about being part of the trial?

Always remember that entering a clinical trial is voluntary and you may withdraw at any time. Withdrawing from the trial will mean you are no longer able to receive the trial medication but your doctor will have further discussion with you regarding treatment.

What happens at the end of the trial?

If you have finished receiving treatment for your cancer, the doctor managing your cancer will either continue to see you at regular intervals or he/she may ask your GP to continue to look after you.

How much will it cost to be on the trial?

Clinical Trials may offer some assistance with transport costs, meal costs and accommodation costs. Patients who travel from out of town may be eligible for the National Travel Assistance Scheme. Please ask your clinical trial nurse.

Where do I receive the treatment?

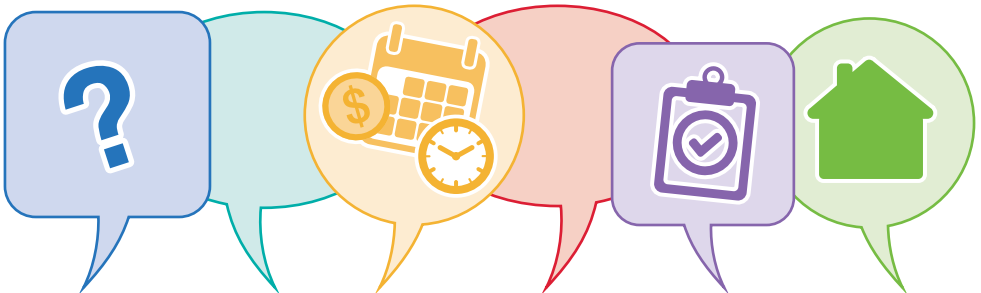
You will receive treatment at Waikato Hospital.

If I do not want to take part in the trial, what treatment will I receive?

You doctor will discuss all your treatment options with you on your first visit. If you do not want to take part in a clinical trial or you are not eligible, you will be offered the best known treatment that is currently available.

How can I take part in a trial?

Each trial has strict guidelines, so ask your doctor if there is a trial that may be right for your particular type of cancer. Enrolment into a trial will be done by the doctor and trials team looking after you.



Why should I join a clinical trial and will I be a “human guinea pig”?

Medicines used in today's world have been tested previously in clinical trials. It is only through your participation that we can hope to improve treatment for cancer in the future.

Your doctor will discuss different treatment choices for your cancer and one of your options may be taking part in a clinical trial. Some patients participate in a clinical trial because other treatments did not work for their cancer, or they were unable to cope with the side effects.

Will the treatment help me and how do I know it is working?

As with any cancer treatment, your doctor recommends the most appropriate treatment available. You will have regular blood tests and scans to monitor your progress.

How long will I be on trial?

This will depend on the trial you are taking part in. Some trials have a definite time frame e.g. two years, whereas other trials you may be on for life.



Patient experiences

We asked a few of our patients to share their personal experiences of participating in a clinical trial. Real names have been used according to patient wishes.

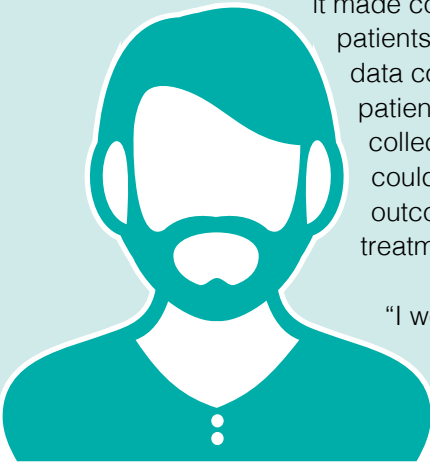
“Why did you choose to participate in an international cancer trial?”

Patient contribution 1 – Terry

“I have recently completed a course of cancer treatment which included chemotherapy and radiation. When I first visited with the doctor to discuss my treatment options, I was told that there was an international trial taking place and if I was interested I could become a patient on this trial.”

“I decided I’d like to participate in this trial. My reason for this was because it made common sense to me, that if I and more patients took part in the trial, the international data collected might assist all future cancer patients. By this I mean, the information collected by all those countries participating could revolutionise and/or improve the outcome, because of the application of treatments for future cancer patients.”

“I would personally recommend that readers of this might consider joining the international trial. I am glad I did.”



Patient contribution 2 – Nel

“When I was advised I had cancer, the first question I asked the oncologist was, ‘are there any trials coming up?’ Luckily for me there was.”

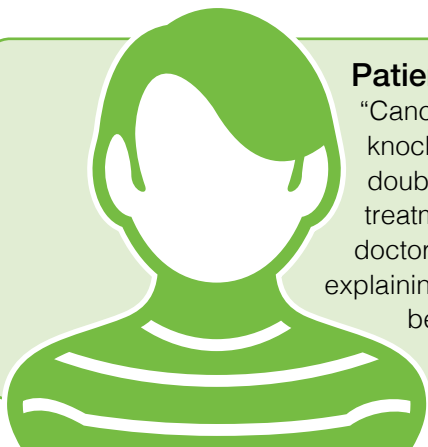
“The care and friendship I have experienced during this time has been amazing, way beyond what I would have ever expected.”

“This has been a journey for me, another stage in my life, which I must say has been a good one, considering the reason I am here.”



Patient contribution 3 – Pera

“Cancer comes calling. Fear and apprehension knocked on my door causing confusion, doubt and much, much more. Since the new treatment, it has put me at ease. Wonderful doctors, nurses so ready to please and explaining all procedures to me. They give the best treatment they can; wonderful people throughout the land. Thank you so much.”



OUR
vision

**Healthy people
Excellent care**



OUR
values

People at heart / Te iwi Ngakaunui

Give and earn respect / **Whakamana**

Listen to me, talk to me / **Whakarongo**

Fair play / **Mauri Pai**

Growing the good / **Whakapakari**

Stronger together / **Kotahitanga**

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