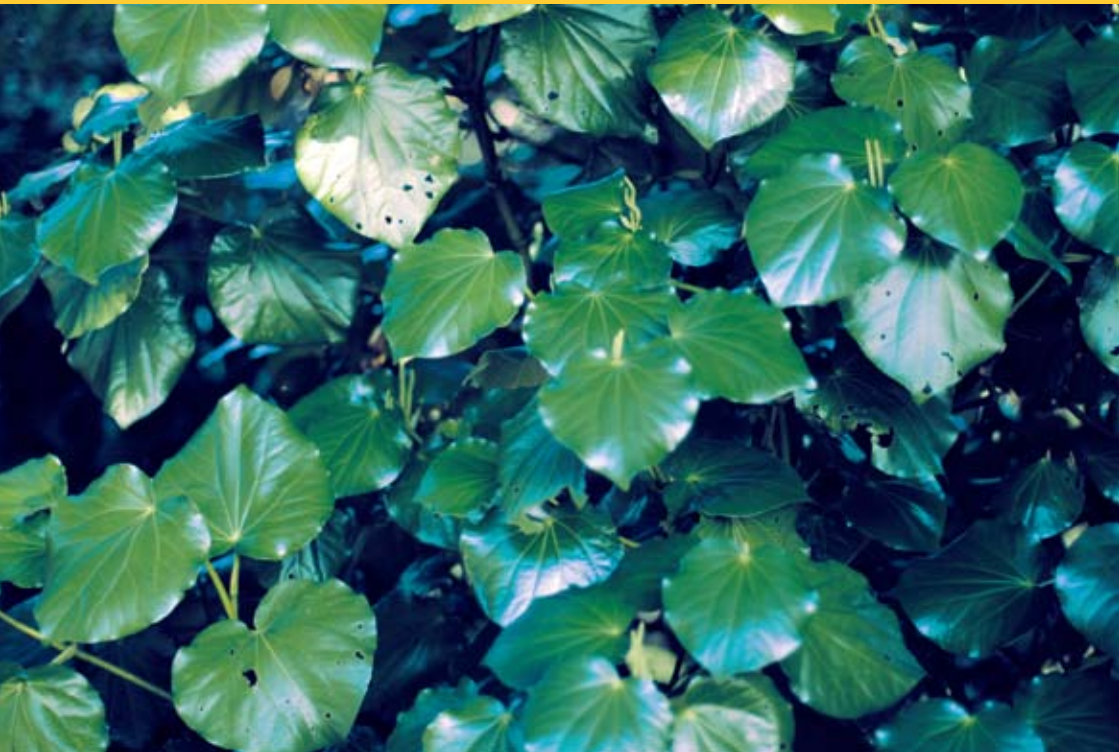


Cancer Clinical Trials



A guide for people considering taking part
in a clinical trial



Cancer Society of New Zealand Inc, PO Box 12700, Wellington.
Copyright © 2010 Cancer Society of New Zealand Inc.

First Edition 2010
ISBN 0-908933-82-7

Publications Statement

The Cancer Society's aim is to provide easy-to-understand and accurate information on cancer and its treatments.

Our *Understanding Cancer* information booklets are reviewed every four years by cancer doctors, specialist nurses and other relevant health professionals to ensure the information is reliable, evidence-based and up-to-date. The booklets are also reviewed by consumers to ensure they meet the needs of people affected by cancer.

Other titles from the Cancer Society of New Zealand/Te Kāhui Matepukupuku o Aotearoa

Booklets

Advanced Cancer/Matepukupuku Maukaha
Bowel Cancer and Bowel Function: Practical Advice
Bowel Cancer/Matepukupuku Puku Hamuti
Breast Cancer/Te Matepukupuku o ngā Ū
Cancer in the Family: Talking to your children
Chemotherapy/Hahau
Complementary and Alternative Medicine
Eating Well/Kia Pai te Kai
Emotions and Cancer
Got Water/He Wai?
Lung Cancer/Matepukupuku Pūkahukahu
Melanoma/Tonapuku
Prostate Cancer/Matepukupuku Repeure
Radiation Treatment/Haumanu Iraruke
Secondary Breast Cancer/Matepukupuku Tuarua ā-Ū
Sexuality and Cancer/Hōkakatanga me te Matepukupuku
Understanding Grief/Te Mate Pāmamae

Brochures

Being Active When You Have Cancer
Being Breast Aware
Bowel Cancer Awareness
Gynaecological Cancers
Talking to a friend with cancer
Questions You May Wish To Ask
Thermography

Cover: *Kawakawa-Macropiper excelsum* is a wonderful plant because it is a warming digestive tonic, an immune support, and is also anti-bacterial. The leaves are heart shaped. It is said that it was sent to Papatuanuku, the earth mother, to heal her broken heart after she was separated from Ranginui, the sky father. Arihia Latham

What are clinical trials?

Cancer treatment clinical trials are research studies to find better ways to treat cancer. These trials look at new drugs or combinations of drugs, new ways of giving radiation treatment, and new types of treatment.

The aim of clinical trials is to find out if a new treatment or procedure is safe; has side effects; works better than the currently used treatment; and helps you feel better.

It is important that men and women of all ages and backgrounds take part in clinical trials so that what is learned will help cancer patients now and in the future.

Clinical trials often compare the most accepted cancer treatment (standard treatment) with a new treatment that doctors hope will be even better.

Some clinical trials don't compare treatments. All of the patients who enter this kind of trial get the same treatment. The purpose is to collect more information about that treatment so we can better understand its effectiveness and the side effects.

There are three phases of clinical trials. Each treatment being tested has to go through all three phases before it can be used:

- **Phase 1** trials look at whether a trial treatment is safe or has any harmful effects.
- **Phase 2** trials look at how well a treatment works.
- **Phase 3** trials test a new treatment against the current standard treatment (some trials are carried out after a drug has been licensed).





Each trial has rules about who can and cannot take part, such as age, sex, your past medical conditions and type of cancer. Some trials are called randomised trials. This means that there are two or more different groups in the trial. People taking part are put into one or other group at random. This 'randomisation' is usually done by a computer. Each group in the trial has a different treatment.

If there are two groups, one group will have the new treatment being tested and the other the standard treatment for their type of cancer. People having the standard treatment are called the 'control group'. A randomised trial that has a control group is called a 'randomised controlled trial'.

Your doctor may invite you to consider taking part in a clinical trial.

Who makes sure my rights are protected?

In New Zealand a trial must be approved by an ethics committee. This committee is made up of health professionals, scientists and members of the public. A trial cannot go ahead without the approval of the ethics committee.

The ethics committee's job is to review all clinical trials (research studies) and make sure they are run safely and fairly. The ethics committee can stop a clinical trial at any stage if they have concerns about the welfare of the people participating.

Under the Privacy Law of New Zealand your privacy is protected. Information collected and recorded as part of a clinical trial will have a special code instead of your name.

What kind of information will I get if I want to take part in a clinical trial?

Before you join a clinical trial, a doctor, nurse, or another person on the research team will explain why the trial is being done, and what will happen during the trial. You can ask them any questions you have about the clinical trial.

You will also be given an information sheet and consent form to read. The consent form will explain:

- why the trial is being done
- the exact plan for each step in the trial
- what side effects you may have
- how the clinical trial may affect your daily life.



Ask the staff about any part of the information sheet and consent form you do not understand. If you decide to take part in the clinical trial, you will be asked to sign the consent form.

Even if you sign the consent form, you can still change your mind and stop at any time. It is important that you understand that if you decide to withdraw from taking part in the trial it will not affect your ongoing medical care.

What are benefits and risks of being part of a clinical trial?

Benefits

- The accepted treatment for the kind of cancer you have (called standard treatment).
- A new treatment that doctors hope will be better than the standard treatment.
- What doctors learn in studies also helps people who may get cancer in the future.

Risks

- It is not known for sure if the new treatment in the trial will help you more than the standard treatment for your cancer.
- Treatments in the clinical trial have side effects. The side effects of the type of drugs you'll have will be explained on the information sheet and consent form.





Do I have to take part in a clinical trial?

No. Taking part in a clinical trial is up to you. It is important to look at all of your treatment options with the help of your family and doctor. This will help you decide if a clinical trial is the best way to treat your cancer.

Be sure you and your family have all the information you need before you decide if you want to take part in a clinical trial.

Questions to ask

Here are some questions to ask before agreeing to take part in a clinical trial:

- Why is the clinical trial being done?
- How will it help me?
- What kinds of tests and treatments are part of the trial?
- How am I protected?
- How could the trial change what I do every day?
- What will happen to my cancer with or without this treatment?
- What other treatments could I get if I don't take part in the clinical trial?
- What are possible short-and long-term side effects for me and my family to think about?
- How do the risks and side effects of the standard treatment compare with the treatment being studied?
- How long will the trial last?
- Will I have to stay in the hospital during the clinical trial?
- If I have to stay in the hospital, how often and for how long?



- How will I be checked after the clinical trial is finished?
- How long do I have to make up my mind about joining this trial?
- Who do I contact with questions regarding the trial?
- Are there any additional costs involved in the treatment?
- Will I be reimbursed for my travel and accommodation costs if I need to be at the hospital for extra visits?
- How will I find out the results of the trial?
- Can I talk to the other patients involved in the trial?
- Can I leave the trial after it has begun?

Write out a list of your questions and concerns to ask your doctor.



More information

To find out more about clinical trials (research studies), ask your doctor or visit the internet at:

www.cancernz.org.nz

www.macmillan.org.uk

www.cancerhelp.org.uk/trials/types-of-trials/about-randomised-trials

www.cancervic.org.au/

www.cancercouncil.com.au

www.cancer.gov

Do you want to know more about cancer?

Call **0800CANCER (226237)** or contact your local Cancer Society.

Information, support and research

The Cancer Society of New Zealand offers information and support services to people affected by cancer. Printed material is available on specific cancers and treatments. Information for living with cancer is also available. The Society also undertakes health promotion through programmes, such as those encouraging SunSmart behaviour, being physically active and eating well and discouraging smoking.

The Cancer Society is a major funder of cancer research in New Zealand. The aim of research is to determine the causes, prevention and effective methods of treating various types of cancer.

We appreciate your support

Many Cancer Society services would not be possible without the generous support of many New Zealanders. You can make a donation by phoning 0900 31 111, through our website at www.cancernz.org.nz or by contacting your local Cancer Society.

Acknowledgements

The Cancer Society would like to thank for their reviews, advice and contributions:

Marina Dzhelali – Charge Nurse Manager, Research, Radiation and Medical Oncology, Clinical Haematology, Wellington Blood and Cancer Centre, Wellington Hospital

Alison Wylie RN – Oncology Research Nurse, Dunedin Hospital, Dunedin

Clinical Research Unit – Blood and Cancer Centre, Wellington Hospital, Wellington

Rachel McLay-Barnes RN – Oncology Research Nurse, Dunedin Hospital, Dunedin

Wendy Thomas – Clinical Nurse Manager, Oncology Trials, Regional Cancer Centre, Waikato Hospital

Kerin Thompson – Clinical Research Co-ordinator, Adult Oncology Research Centre, Auckland Regional Cancer and Blood Service

Consumer reviewers – The Cancer Society wishes to acknowledge the input and expertise of our consumer reviewers.

Thanks to those who volunteered to have their photos taken for this booklet.

Meg Biggs, Julie Holt, Michelle Gundersen-Reid – Cancer Society Information Nurses

Sarah Stacy Baynes – Information Manager

Louise Goossens – Charge Medical Photographer, Photographic Unit, Wellington School of Medicine and Health Sciences, Wellington

Brochure adapted with permission from:

National Cancer Institute/NCI Eastern Cooperative Oncology Group/ECOG.





www.cancernz.org.nz

ANY CANCER, ANY QUESTION 0800 CANCER (226 237) Cancer Information Helpline

