Leukaemia Foundation
VISION TO CURE
MISSION TO CARE

FACT SHEET

Clinical Trials: Latest treatments and best options

About us

The Leukaemia Foundation is the only national not-for-profit organisation dedicated to the care and cure of patients and families living with leukaemia, lymphoma, myeloma and related blood disorders.

We invest millions of dollars in the work of Australia's leading researchers to develop better treatments and cures and provide free services to support patients and their families.

We receive no ongoing government funding. We rely on the generosity of the community and corporate sector to further our Vision to Cure and Mission to Care.

We can help you

Our range of free services supports thousands of Australians, from diagnosis, through treatment and beyond. To learn more, please call 1800 620 420 to speak with one of our Support Services team.

You can help us

There are many ways that you can help us to improve the quality of life for people with blood cancer. From making a donation, to signing up for an event; from volunteering, or joining us as a corporate sponsor - please call 1800 500 088 or go to www.leukaemia.org.au to learn more.

Last updated: Feb 2011

Participation in a clinical trial can provide access to cutting-edge, potentially life-saving and life-enhancing treatments.

A clinical trial is a research study that helps to determine whether a new drug or device is safe and/or effective. Each study is designed to answer questions and find better ways to screen, diagnose, prevent or treat a disease or condition. They may be sponsored by drug manufacturers, government, and organisations including the Leukaemia Foundation.

What happens during a clinical trial?
Each study has a plan that maps out the study–what will be done, by whom, when and why. This protocol also explains who is eligible to participate in a trial and what is expected of them. If you are eligible, a team of doctors and nurses will manage your care. Trials are held at hospitals and research centres around the country.

What are the benefits of participating in a clinical trial?
Participation in a clinical trial gives you access to cutting-edge, potentially life-saving and life-enhancing treatments. Your participation contributes to the advancement of medicine and helps others who share or may develop your condition.

Should I consider taking part in a clinical trial?
Before signing up, learn as much as possible about the trial, then discuss your options with your doctor. Clinical trials are not right for everyone, nor is every patient able to participate. Before starting any trial, you should understand what will happen during the study, what is expected of you, the care you will receive and the costs that you may have to cover. You will then be given a written consent form to sign.

What will the cost be?
You will not need to pay any money to participate in a clinical trial, over and above what you may pay for standard treatment. Any medical tests and medical care related to the trial are also at no cost. Some studies compensate you for other expenses such as parking and travel. Private insurers often do not cover the costs related to a clinical trial, so you will need to check with your health care provider.

What are the risks?
The risks depend on the type of treatment being studied and the health of the individual patient. For some, there could be unpleasant, even serious, side effects. Often these side effects are temporary and end when the treatment stops. There are both known and unknown risks with any trial. Be sure you understand the known risks before you join any study.

Isn't it dangerous to take an experimental drug?
Whilst most clinical trials involve some risk, researchers must follow strict scientific guidelines and ethical and legal codes to ensure that you are protected. Studies need to be approved by an Independent Ethics Committee (IEC) or Institutional Review Board (IRB), or an equivalent, depending upon the regulations of the country where the trial is being carried out. This committee – made up of scientists, doctors, and other people from the local community (e.g., consumer representative, ethics expert) – reviews each study to see that it is designed to protect the patient and to ensure that the benefits of the study outweigh the risks. Each trial must meet the Good Clinical Practice (GCP) standard. GCP is an ethical and scientific quality standard that ensures that the rights, safety and well being of study participants are protected.

Continues...

How long will the study last?
The length of each study is different. The trial's protocol document will provide you with information on how long the trial lasts and what is expected of you.

If I start a trial, do I have to stay in it?
No, you can leave the trial at any time. Even if you signed paperwork, you may still leave the study if you choose. You have the right to change your mind at any time.

Will I still get regular medical care?
As a participant of a clinical trial, you would receive excellent medical care from a team of doctors, nurses, researchers, social workers and other health professionals who are on hand to manage your condition. The trial's protocol may require you to visit the study site more often to check in with your study doctor. Plus you may receive more tests and treatments than usual.

What if I get a placebo?
It is very unusual for a person to receive a placebo in a clinical trial in Australia and you would be warned of this possibility before commencing a trial. As a rule, trials of drugs for cancer do not use a placebo but rather participants receive an approved drug already in use or the approved drug plus the drug being studied. In "randomised" trials, researchers use a computer to randomly decide who will get the real drug and who will receive the standard treatment. In a "blinded" trial, neither the researchers nor you will know if you're receiving the experimental or standard drug. The randomised system ensures the process meets the scientific requirements of the trial.

Does my doctor have to be one of the doctors involved in the trial for me to take part?
No, your doctor does not have to participate in the trial in order for you to join. Trial researchers may provide you with care or they will want your regular doctor to care for you. Whether or not your doctor participates in the trial, you will need to see him or her for general medical care. Sometimes you may have to attend a different treatment centre and have a new doctor to participate in a trial.

How do I find out if I'm eligible?
Each study's protocol has guidelines stating who can and cannot join the clinical trial. The criteria vary by study and could include your age, gender, medical history, current health status and the particular type or stage of disease you may have. Before you join the trial, you will be asked to sign an informed consent form. Then a doctor or nurse will assess your medical history, perform a physical exam and perform laboratory tests to determine whether you meet the eligibility criteria.

Is everyone with my disease eligible?
No, only people meeting the study's guidelines, or eligibility criteria, may join the study. If you are found to be ineligible, you should talk to your doctor to see if there is another clinical trial that may be right for you.

What would be required of me if I participate?
The doctor will first talk to you about informed consent. This is a process by which you will learn the details of the trial – what is involved, the purpose of the study, the tests and procedures that will be used, and the risks and benefits. You will then be given a written consent form, which explains the study. If you agree to take part, you will be asked to sign the form. If there is something on the form you do not understand, ask questions. Study doctors and nurses are available to help you understand the risks and benefits of the trial.

What happens at the end of the trial – will I still be able to receive the drug?
After you complete the study, you may or may not be able to continue receiving the drug. In some cases the treatment will not be made available to you again until it is government-approved. Once the trial ends, researchers analyse the data and if the study is considered pivotal and results are positive they will be submitted to the national health authority for approval. During the approval process some pharmaceutical companies choose to continue to make the drug available through a pre-approval access program.

How do I find a clinical trial?
First, talk to your doctor. He or she will be able to access an up-to-date listing of clinical trials. You may also want to call patient advocacy groups and local university medical centres. The Australasian Leukaemia and Lymphoma Group has a website which lists currently open clinical trials in blood and bone marrow cancers like leukaemia, lymphoma and myeloma. See www.petermac.org/allg and information from Australian clinical trials sites listed on the Leukaemia Foundation's web site: www.leukaemia.org.au.