Phase 1 Clinical Trials

Information for Patients and Families

Find out more about Phase 1 Clinical Trials in CancerControl Alberta

Treatment

Cancer Care Alberta

Phase 1 Clinical Trials

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What is a phase 1 clinical trial?

Clinical trials test new methods that will help diagnose, treat, manage and prevent cancer. Phase 1 clinical trials test the safety of new treatments, and how well they work.

There are many different types of phase 1 trials. Some are done:

- with a treatment that has never been given to people before. This is called a “first in human” study.
- with a combination of treatments — often a new drug combined with older drugs already used.
- to see if a drug or drug combination is safe in patients whose liver or kidneys are not working properly.

What are phase 1 clinical trials for?

Phase 1 trials are very important — they are the first step in finding new and better cancer treatments.

Phase 1 trials are used to:

1. decide on the correct amount (dose) of the treatment to be used in people.
2. collect information on side effects patients have.
3. find out what the treatment is doing in the body.
4. find out what the body is doing to the treatment.
5. get a sense of what types of cancer the treatment can control.

How do phase 1 clinical trials keep patients safe?

All clinical trials:

- follow strict ethical standards that are in place to protect the health and safety of patients.
- have been reviewed and approved by a scientific and ethical review board.

Every trial that takes place has an action plan to follow. This plan is called a **protocol**. A protocol is a set of rules that guides the trial and describes:

- what will be done.
- how tests and evaluations will be done and why.
- how often a patient has to be at the hospital.

Who can take part in a phase 1 trial?

Phase 1 trials are generally for cancer patients who have:

- no standard treatment (a recommended treatment based on past studies and experience) for their cancer.
- had all available standard treatments but these treatments are no longer working.
- advanced cancer where adding trial medications to standard treatment may help you live better or longer.

Some phase 1 trials look for patients with specific cancer types.

To participate in a clinical trial you must be well enough to attend appointments and take the trial treatment over time.

Getting Involved in a Phase 1 Clinical Trial

How do I know if I can join a phase 1 trial?

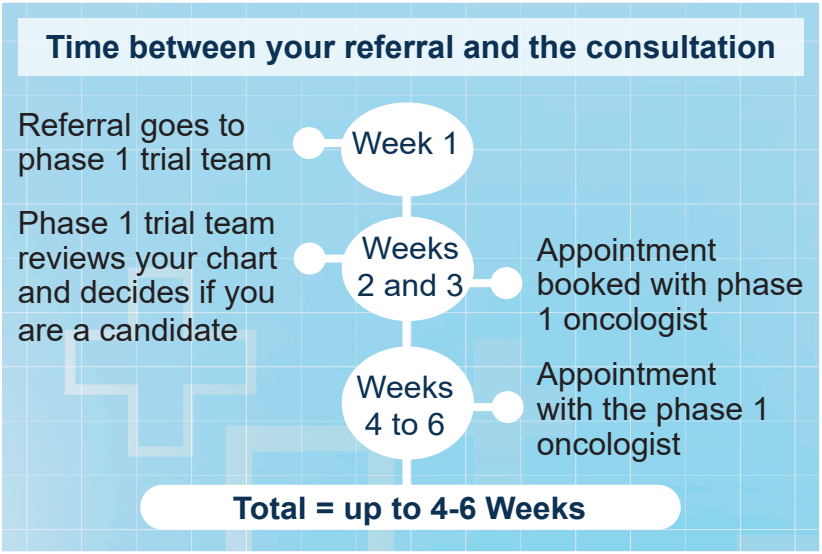
Your oncologist (cancer doctor) will ask the phase 1 trial team to review your chart. When reviewing your chart, the team will decide if there are any trials you might be able to join.

The team will let your oncologist know if you meet the criteria for a current phase 1 trial. They will book an appointment for you to talk with a phase 1 oncologist.

If there are no phase 1 trial options for you, your oncologist will let you know, and no appointment will be booked.

How long does it take to get a consultation with the phase 1 trial team?

If your oncologist refers you to the phase 1 trial team, your consultation will be up to 4 to 6 weeks after the phase 1 team gets the referral (see below).



What happens at the phase 1 consultation?

You will meet with a phase 1 oncologist at the consultation. The oncologist will talk to you more about phase 1 trials and tell you about any trials you may be able to join.

The phase 1 oncologist will give you a consent form for any phase 1 trial they think might be a safe option for you. This is for your information only.

After reviewing these consents call the phase 1 nurse at the number on your consents. You will decide together how best to move forward.

You may wish to ask some of these questions to help you decide if the phase 1 clinical trial is right for you:

- What are the pros and cons of this trial treatment?
- What will I be asked to do?
- Will this require extra time or travel?
- Will any of my expenses be paid (for example parking, or travel)?
- What are the side effects and risks?
- How long will I be in the trial?
- How will I know if it is working?
- What will happen if I decide to leave the trial?
- How can I find out the results of the trial?

What is a consent form?

The consent form explains the trial in detail and describes:

- why we are doing the trial
- the treatment you will receive
- how often you will need to be at the cancer centre doing the clinical trial
- the known and possible side effects of the trial drugs
- the benefits and the risks
- anything else you need to know about the trial

Your phase 1 trial oncologist will ask you to take the consent form home and read it. You need to think about whether or not you would like to participate. It is important to **talk with your health care provider about the trial and ask any questions you may have before you sign any consent**.

Once you make a decision, call our phase 1 trial team to let us know if you would like to participate or not.

When it is almost time for you to start on the trial the team will call you. If you still want to participate in the trial you will be asked to sign the consent. Signing the consent means you agree to take part in the clinical trial.

What happens if I change my mind later?

Even after you sign the consent form, **you are free to leave the trial at any time**. You are in full control and do not need to give a reason if you want to leave. Your personal information will remain private and confidential.

The quality of any other care you are receiving will not change if you decide to leave the trial.

What to Expect with a Phase 1 Clinical Trial

How long before I start the phase 1 trial?

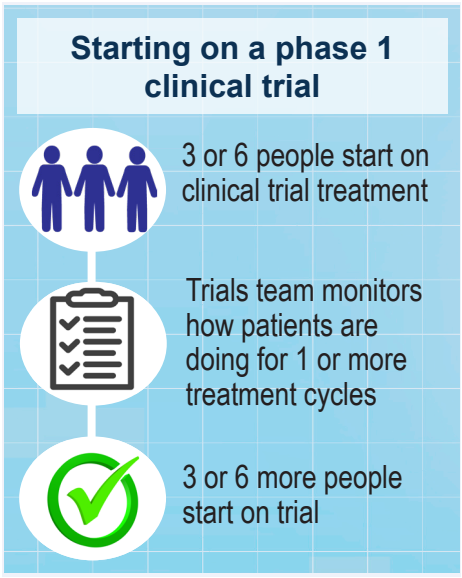
It depends on the trial, but it may take **weeks or even months after your consultation** before you start.

Each cancer centre doing a trial can only start a certain number of patients. This is decided by:

- the drug company that is running the phase 1 clinical trial.
- how many other cancer centres are participating in the clinical trial.

We take extra steps to keep people safe during phase 1 trials. People are started on trials in very small numbers and monitored carefully. We only have a certain number of spots.

The phase 1 trial team will often not be able to tell you exactly how long it will be before you can start the trial. The way phase 1 trials are run (see beside) means start times are uncertain. We will do our best to get patients on the appropriate phase 1 study as soon as possible.



What type of treatment will I receive?

In phase 1 studies, everyone gets the new cancer treatment. You will not get sugar pills (placebos).

How often will I have to go to the cancer centre?

You will have many clinic visits and appointments for a few different reasons:

- We know less about the side effects and reactions you may have since this is phase 1 of testing of a new drug. This means we need to monitor you more closely.
- This is mainly for your safety but also because the trial has a set schedule for tests and evaluations.
- Sometimes treatments may be delayed based on blood work results or side effects that you may have. We will need to make extra appointments with you to monitor these changes and get you ready to start on the trial medications again.

How long will the appointments be?

Some of your visits may be short but some will also be longer. It just depends on what needs to be done that day.

Your consent form will outline the time commitment.

Phase 1 trial appointments may happen more often and take up more time than standard treatment or phase 2 or 3 trials. If you agree to participate in a phase 1 trial, you will need to come to your scheduled appointments. If you cannot do this, the phase 1 trial team will not be able to monitor you safely. You will need to be removed from the trial.

Think about the time commitment before you decide to participate.

Where will the phase 1 trial activities and procedures happen?

All procedures will be done at the cancer centre doing the clinical trial in Alberta unless it does not have the service needed. If this happens, you will go to a medical facility that does (for example, some patients need eye exams which happen at another local clinic).

Who is in charge of my care?

The phase1 trial team will manage your participation in the trial if you start on a trial treatment. During the trial the team will help manage your cancer and health needs related to the clinical trial treatment.

Your family doctor will be a partner in care and look after other health conditions you may have.

Many patients referred to the phase 1 trial team do not have any standard cancer treatment options left. In this case, patients are often followed by their oncologist and family doctor while they wait to hear about clinical trial options.

Talk with your regular oncologist! They can tell you which doctor you should call if you need medical attention while you are either waiting for a phase 1 trial consult or waiting to start a clinical trial.

Find this and other Alberta cancer care resources at your cancer centre and online:

www.cancercarealberta.ca

www.albertacancerclinicaltrials.ca

This book is meant to support the information your health care team gives you. It does not replace any information that your health care team gives you.

The information is to be updated every 3 years, or as new clinical evidence emerges. If there are any concerns or updates with this information, please email cancerpatienteducation@ahs.ca.

Cancer Care Alberta

Leading care through compassion, courage, learning and discovery

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