



Understanding phase 1 clinical trials

Experimental cancer medicine team (ECMT)



Contents

Introduction	3
What is a clinical trial?	3
What is a phase 1 clinical trial?	3
What are phase 1 drugs?	4
How are phase 1 clinical trials conducted?	4
Who can take part in a phase 1 trial?	5
What happens to me if I decide to take part in a phase 1 clinical trial?	5
Patient pathway	7
What are the possible benefits of taking part in a phase 1 clinical trial?	8
What are the possible disadvantages of taking part?	8
Will the trial help my cancer?	9
What will happen if I get side effects?	9
How long will I be on the trial?	9
What will happen when I finish the trial?	10
What happens if I decide not to take part?	10
Can I change my mind?	10
What happens to the drug after a phase 1 trial?	10
Contacts	11

Christie website

For more information about The Christie and our services, please visit **www.christie.nhs.uk** or visit the cancer information centres at Withington, Oldham or Salford.

Introduction

This leaflet provides information for you, your family and friends to explain what phase 1 clinical trials are and how they are carried out.

Please take time to read this information carefully, and discuss it with your family and friends if you wish. You are entirely free to decide whether or not to take part in a trial. If you choose not to take part the standard of care you are given by your own doctors will not be affected.

What is a clinical trial?

A clinical trial is a controlled way of finding out more about new drugs or treatments. Clinical trials are important as they provide us with essential information and knowledge, leading to better treatments and management of cancer. The trials are carefully designed so that your doctors can find out about the safety and effectiveness of new treatments. Many drugs that have been tested in clinical trials are now in common use, such as Tamoxifen for breast cancer or carboplatin, a chemotherapy used in a range of cancers.

What is a phase 1 clinical trial?

A phase 1 clinical trial is the first stage in testing a new drug in patients. During a phase 1 trial your safety is very important, and your doctor and research team will need to monitor you closely for side effects throughout the trial. Blood samples are often collected to check how much of the drug is present in the blood and for how long. For these reasons, phase 1 trials are performed by specialist centres such as The Christie.

Phase 1 trials help your doctors find out:

- if a new drug is safe
- if it has side effects
- how much of the drug can be given safely, and how often
- whether the new drug is effective against cancer.

Phase 1 trials have small numbers of patients and often patients receiving these phase 1 treatments have received other cancer treatments previously. Often their cancer has stopped responding to their current treatment or their cancer may have come back. These patients sometimes do not have any proven standard treatment options remaining for their cancer.

What are phase 1 drugs?

Scientists are constantly striving to understand more about cancer. Phase 1 drugs will have been found to kill cancer cells in laboratories and will have been carefully studied to look at how safe they are, and what the best way is to give them to patients. These tests will have involved testing the experimental drugs in animals to find out about safety and dose of the drug.

How are phase 1 clinical trials conducted?

Typically the first group of patients are given a small dose of the trial drug or combination of trial drugs that is expected to be safe. If none of the patients experience any serious side effects then the next group of patients will receive a higher dose. The dose of the drug increases in successive patients until side effects are seen that your doctors believe makes it unsafe to increase the dose further.

This is called the Maximum Tolerated Dose. Once this happens, higher doses of the drug are not given. The trial may recruit further patients at a tolerated dose to confirm that the dose of the drug is correct.

At The Christie, phase 1 trials are conducted in highly specialised units with doctors and nurses who are experienced at looking after patients with cancer who are receiving treatment in these types of clinical trials. They will monitor you very carefully during the course of your treatment to make sure you are safe.

Who can take part in a phase 1 trial?

For your safety, all phase 1 trials have strict guidelines about who can take part. All patients must be well in themselves and usually should not have received any treatment for their cancer in the past 4 weeks.

Each trial has its own rules about which patients can or cannot be treated with the trial drug. Your doctors will decide if you meet the requirements for the phase 1 clinical trial. If there is a reason why a phase 1 trial may not be appropriate for you (for example you are not well enough so there is an increased chance of serious side effects) this will be explained to you by the doctor in the clinic.

What happens to me if I decide to take part in a phase 1 clinical trial?

If you decide that you would like to take part in a phase 1 clinical trial your case will be discussed at a weekly trial allocation meeting. The team will try to identify a clinical trial for you that, in their opinion, has a chance of working against your cancer. Please note, we are not able to find suitable trials for every patient interested in phase 1 trials.



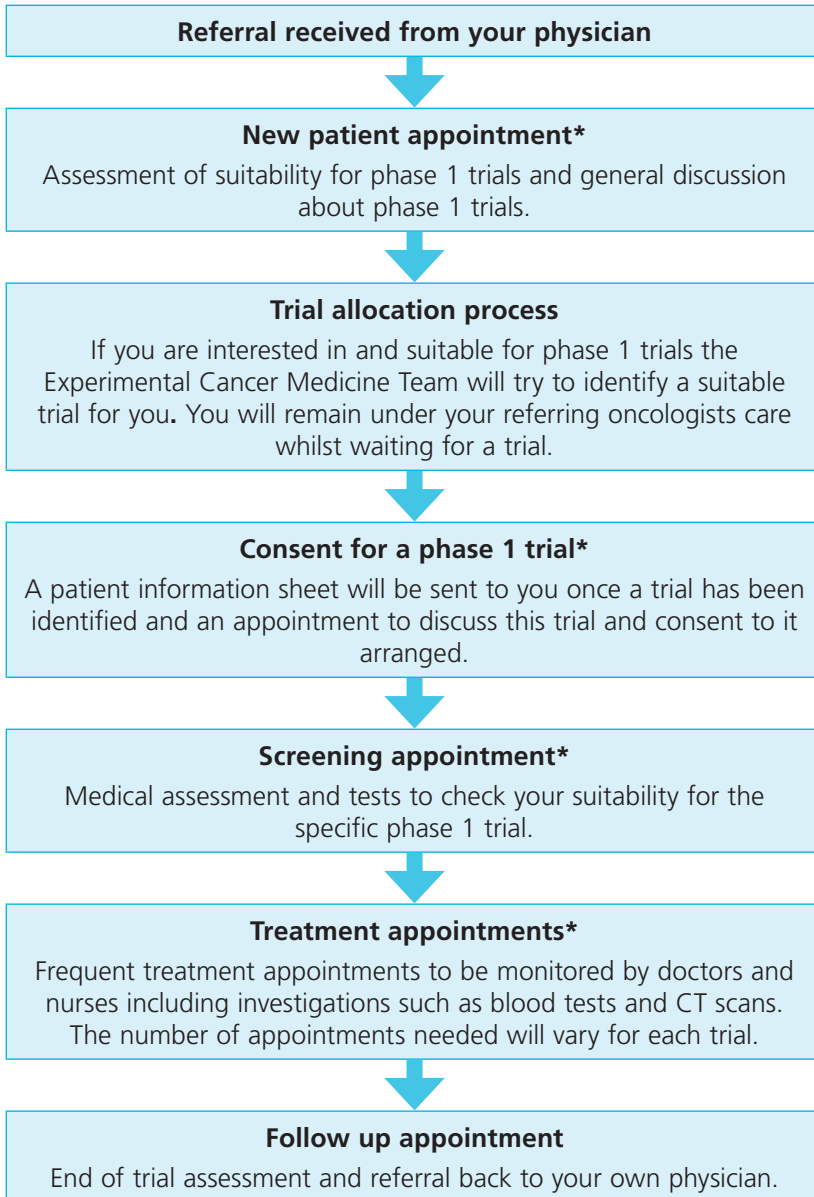
Whilst you are waiting for a phase 1 trial you would remain under the care of your referring oncologist. Once a phase 1 trial has been identified we will give you a detailed 'patient information sheet' that explains about the drug(s) which you will receive including any known side effects, and details of the visits and extra tests required.

You will be given enough time to read and understand the information. If there is anything you do not understand or that concerns you in the patient information sheet, please feel free to contact us or write it down.

We will ask you to sign a consent form agreeing to accept the treatment that you are being offered. The basis of the agreement is that you have had The Christie's written description of the proposed treatment and that you have been given an opportunity to discuss any concerns. You are entitled to request a second opinion from another doctor who specialises in treating this cancer. You can ask your own consultant or your GP to refer you. Your consent may be withdrawn at any time before or during this treatment. Should you decide to withdraw your consent then a member of your treating team will discuss the possible consequences with you.

After you have signed the consent form your doctor will request a series of tests which may include blood tests, heart monitoring, eye tests and other tests such as CT scans. These are called 'screening tests' to ensure that you meet the requirements to take part in the phase 1 clinical trial. If so, we will then give you a date to come to hospital for the start of your treatment.

Patient pathway



*Patients may not be suitable for phase 1 trials or may not wish to participate in phase 1 trials. The decision will be discussed with the patient and a referral back to their physician made.

You may need to stay in The Christie overnight for monitoring and blood tests when you receive the trial drug for the first time. After this initial drug administration you will have to visit the hospital frequently, usually weekly. Most visits are outpatient visits and last for a few hours, but some visits can last up to 12 hours and you may need to stay overnight. Hospital visits may involve extra tests which can include blood sampling, scans, heart monitoring or eye tests.

What are the possible benefits of taking part in a phase 1 clinical trial?

- You will receive treatment with a new anti-cancer drug that is only available in a phase 1 clinical trial.
- You will have close, regular check-ups including blood tests, CT scans or other tests which you may find reassuring.
- You will be monitored by a team of experts who will guide and support you throughout your treatment.
- You will be helping to improve cancer treatments for the future.

What are the possible disadvantages of taking part?

- You will need to come to hospital more often (usually every week).
- Some visits could require you to stay in the hospital all day or overnight.
- There may be extra tests which could increase your worry about your cancer.
- You may have to complete extra paperwork.
- You may experience side effects from the treatment.

Will the trial help my cancer?

The purpose of phase 1 clinical trials is to find out the safety of new anti-cancer drugs in patients with different types of cancer. Therefore, it may not be possible to give you any information about the effectiveness of these drugs against your cancer. There is only a small chance that your cancer will respond/shrink with the new drug.

It is estimated that, for every six patients who are treated in phase 1 clinical trials, approximately one patient may have some benefit.

What will happen if I get side effects?

Your doctor and nurse will monitor you regularly and carefully during your treatment. If you get any side effects it is important to inform your doctor or nurse as soon as possible. The trial drug may need to be temporarily delayed to allow the side effects to get better. Sometimes the trial treatment will need to be reduced or even stopped if the doctors are concerned that the side effects are too severe. You can also decide to stop if you decide you do not wish to continue on the trial but you need to inform your doctors if you want to stop the trial drug.

How long will I be on the trial?

The trial treatment may continue as long as you are not experiencing any serious side effects, your cancer appears to be controlled and you want to carry on with the trial. Some trials only continue for a few weeks or months. The information about the length of the trial will be given to you before you sign the consent form.

What will happen when I finish the trial?

About 4 weeks after the last dose of the trial drug the doctor or nurse will see you. You may need further tests and we will then discuss your future care which may mean returning to the care of your original cancer specialist or your GP.

What happens if I decide not to take part?

If you decide not to take part you do not have to give a reason and your decision will be respected. Your doctor will talk to you about other options for your care.

Can I change my mind?

Yes, you can change your mind and leave the trial at any time without giving a reason.

What happens to the drug after a phase 1 trial?

Your doctors will collect the results of the trial to decide if the drug is safe for patients and how effective it is against cancer. If the drug is found to be safe and effective, the

drug will undergo further tests called phase 2 and phase 3 trials to look at whether the new treatment works better than the standard treatment for a particular type of cancer.

We hope you have found this information helpful. We are happy to answer your questions about phase 1 clinical trials at The Christie.



If you have any questions, please feel free to contact us on one of the numbers listed.

Contacts

ECMT research secretaries telephone numbers:

0161 918 7672

0161 918 2379

0161 918 7894

If you need information in a different format, such as easy read, large print, BSL, braille, email, SMS text or other communication support, please tell your ward or clinic nurse.

The Christie is committed to producing high quality, evidence based information for patients. Our patient information adheres to the principles and quality statements of the Information Standard.

If you would like to have details about the sources used please contact the-christie.patient.information@nhs.net

Contact The Christie Hotline for
urgent support and specialist advice

The Christie Hotline: 0161 446 3658

Open 24 hours a day, 7 days a week

Visit the Cancer Information Centre

The Christie at Withington **0161 446 8100**

The Christie at Oldham **0161 918 7745**

The Christie at Salford **0161 918 7804**

Open Monday to Friday, 10am – 4pm.

Opening times can vary, please ring to check
before making a special journey.

The Christie NHS Foundation Trust

Wilmslow Road
Manchester M20 4BX

0161 446 3000

www.christie.nhs.uk



The Christie Patient Information Service
September 2021 – Review September 2024

CHR/XRT/1066/27.11.14 Version 3