Helpline (freephone) 0808 808 5555
information@lymphoma-action.org.uk
www.lymphoma-action.org.uk

About clinical trials

This page is about clinical trials for lymphoma: what they are, why they are done, how they are organised and what they involve for those who take part.

You might also find it helpful to visit **lymphoma-action.org.uk/AboutClinicalTrials** to watch our award winning films of clinical trial professionals from University College London Hospital (UCLH) and hear personal experiences from people who have taken part in a clinical trial.

On this page

What are clinical trials?

Clinical trials are medical research studies involving people. They often test new treatments but they can also be used to study other aspects of a disease, such as how it develops or the best way to diagnose it. This page focuses mainly on treatment-related clinical trials.

Every new treatment for lymphoma needs to be tested in clinical trials. It is the only way that treatments for lymphoma can be improved in the future.

Clinical trials testing treatments

A new treatment can only be approved by the European Medicines Agency for widespread use (known as '**licensing**') after it has been thoroughly tested to make sure the benefits of the treatment outweigh any risks. The results of treatment trials are needed for a drug to be licensed.

Clinical trials testing treatments aim to find out if new treatments, or new ways of using existing treatments, are better than current standard treatments. Clinical trial organisers do not know whether the new treatment is better than the standard treatment before the trial has been completed. The standard treatment might be just as good as, or even better than, the new treatment.

Treatment trials can test:

- **A new treatment** – if it works; if it is safe; whether it is better than the current standard treatment; if it can work in combination with other treatments; how it works and how your body processes it.
- **Existing treatments** – comparing one treatment with another; comparing different ways of using existing treatments (for example, a different dose or a different way of giving it); or testing if treatments used for other diseases could help people with lymphoma.

Other types of clinical trial

Trials that don't involve treatment might be used to study:

- what causes lymphoma
- the best ways to detect or diagnose lymphoma
- how genetic changes (mutations) in lymphoma cells might be used to design or choose treatments
- the best ways to monitor response to treatment and follow-up after treatment
- how lymphoma affects your quality of life.

If you are considering entering a trial that does not involve treatment, talk to your medical team about exactly what is involved.

There is more information on the different types of trials in our **clinical trials booklet**.

How are clinical trials designed?

Trials are organised to answer questions in a scientific way. They are also designed to be fair and safe for the people who take part.

Phases of trials

Clinical trials of new treatments are planned based on the results of laboratory and animal studies to make sure the trial is as safe as possible for the people taking part. Treatment trials in humans are normally organised in phases. More is learnt about a treatment as it goes through the different phases. If a treatment is not successful in one phase, it can't go on to the next.

- **Phase 1** trials test the safety of a new treatment in a small number of people and often aim to find out the best dose of the drug to use in later studies. Phase 1 trials might be the first time a treatment has been tested in people (known as 'first-in-human' trials). Phase 1 trials are usually only carried out in people who have no other treatment options.
- **Phase 2** trials aim to find out more about the safety and effectiveness of the new treatment in a larger group of people.
- **Phase 3** trials compare the safety and effectiveness of the new treatment (or new way of using an existing treatment) against the standard treatment in a larger group of people.
- **Phase 4** trials are done after a new treatment has been **licensed**, to monitor its effectiveness and any side effects that occur with widespread use.

Phase 1 and 2 trials are sometimes called 'early phase' trials. Phase 3 and 4 trials are sometimes called 'late phase' trials.

Trials that do not involve treatment are not done in phases because they do not involve taking medication.

Randomisation

When trials compare one treatment against another, they are often randomised. This means that instead of a doctor choosing which treatment you have, a computer randomly assigns the people taking part in the trial to different treatment groups. These are sometimes called treatment 'arms'.

If you are in a randomised trial, you can't choose which treatment you have and neither can your doctor.

Randomisation is used to make sure that the trial is fair. It means the results from each group can be compared scientifically.

Blinding

In some trials, you do not know which treatment you are having. This is called a 'blind' trial. If your doctor doesn't know either, the trial is called 'double-blind'. Blinding is used because knowing what treatment you are on could influence your or your doctor's expectations about it. This could affect the results of the trial because people can't help being influenced by knowing what the treatment is. The trial organisers keep a record of who is having which treatment so they can tell your doctor if any problems occur.

Placebos

A placebo is a dummy treatment – it doesn't have any active medication in it. It is used to make sure that the results of a trial aren't affected by whether or not participants know they are having active treatment.

Many lymphoma trials do not use placebos. If they do, placebos are used in addition to standard treatment. You don't have placebo treatment on its own. For example, participants in a placebo-controlled trial might be treated with either:

- standard treatment plus the new treatment
- standard treatment plus a placebo that looks the same as the new treatment.

If you take part in a trial that uses placebos, your trial team will tell you. However, you won't know whether you are having the placebo or active treatment.

Planning clinical trials

Setting up any trial takes a long time. Clinical trials in the UK are governed by strict laws. These laws protect the people taking part and help to ensure that trials are as safe as possible.

Organising a trial usually involves the following process:

- **Making a proposal**: Clinical trials are set up by individuals or organisations who design a trial to answer a question. A trial may be organised by a university or a pharmaceutical (drug) company.
- **Getting funding**: Trials are very expensive. Funding has to cover research staff, administration, drugs and tests, hospital stays, analysis of the results and the costs of following-up participants, sometimes long after treatment has finished. Cancer trials in the UK are usually funded by a pharmaceutical company, a national charity (for example **Cancer Research UK** or **Bloodwise**) or a government organisation. Funding often comes from a combination of sources.
- **Developing a protocol**: Every trial needs a document that describes the study in detail. This is called the trial 'protocol'. The doctors and nurses treating you have to follow the procedures described in the protocol to make sure everyone who participates in the trial is treated in the same way. The protocol includes information on: why the research is needed; who is able to take part; how many people are needed for the trial; the treatments, tests and methods involved; how participants will be monitored and for how long; how long participants are expected to be involved in the trial; and when the trial will end.
- **Getting approval**: All trials must be approved by an independent ethics committee and by the **Medicines and Healthcare products Regulatory Agency (MHRA)**, a government organisation that regulates the use of medicines in the UK. These agencies look at the protocol carefully to make sure the researchers are working in the participants' best interests.

Once the protocol has been approved and funding has been secured, investigators can begin to find people to take part in the trial. This is called 'recruitment'. If a trial is running at your centre and your doctor thinks you could be suitable, they might invite you to take part. You can choose not to get involved. Your decision won't affect the care or treatment your doctor gives you.

If you do consider taking part in a trial, you might want to read some of the advantages and disadvantages of taking part. Take time to think about all the information you get. Ask your **doctor questions** to make sure you understand what is involved. You can show the information to someone else, such as a family member or your GP, if you want to.

What happens during a clinical trial?

Most treatment trials follow a similar process:

- **Informed consent given**: Your doctor explains the trial and you are given a 'patient information sheet' (PIS) to read. Although it is called an information sheet, it is actually a leaflet and it may be several pages long. This gives you details about the trial so you can make an informed decision on whether or not you want to take part. You can **ask as many questions as you want**. You can show the information to someone you trust like a family member or your GP if you want to. If you decide to take part, you are asked to sign an informed consent form to show that you understand the information you have been given and agree to take part. You usually have to wait at least 24 hours between being given the information sheet and signing the informed consent form. This is to make sure you have had time to think about it.
- **Eligibility assessed**: Once you agree to take part, you have tests to check if you are suitable for the study. You can only take part if you meet strict criteria called 'eligibility criteria'. If you do not meet the requirements for the study, you will not be able to take part in the trial. Your doctor will discuss other options with you.
- **Treatment allocated**: If you are eligible for the trial, you are usually assigned to a treatment group, which determines what treatment you will receive.
- **Treatment**: During the treatment period, you visit the hospital regularly for treatment and tests. You might be given some treatment to take at home. Details about tests and treatments are provided in the information sheet. This tells you how the treatment is given, how often you have it and how long you are treated for.
- **Follow-up**: When treatment is finished, you go to the hospital regularly for check-ups to see how you are doing.

Trials are monitored closely throughout to make sure any problems are picked up and dealt with quickly. The protocol can be changed if necessary during the course of the trial. For example, the trial might be expanded to recruit more people, or the closing date might be changed if recruitment is slower than expected.

A trial may be stopped early if there are concerns about safety or if it is not likely to come up with a meaningful result. This can happen if the organisers have difficulty recruiting enough people to take part. If it becomes obvious that one group is doing much better than the other groups, the trial might close early and everyone might switch to the better treatment if possible.

Who can take part in a clinical trial?

In order to join a clinical trial, you must meet a strict set of criteria. These eligibility criteria are important in making the study as safe as possible for the people taking part. They also make sure that people in all the treatment groups have similar characteristics at the start of the trial. This means that any differences found in the trial are likely to be due to the treatments rather than any other factors.

- **Inclusion criteria** set out who **can** join the trial. For example, the exact type of lymphoma participants must have, the stage of their lymphoma and whether they have already had treatment or not. The criteria usually give an age range for participants.
- **Exclusion criteria** set out who **can't** join the trial. For example, certain previous treatments might interact with the study drugs so you can't join the trial if you've had them. Other criteria relate to safety – if you have other medical conditions you might not be able to join. Pregnant and breastfeeding women are normally excluded from clinical trials to prevent harm to the baby.

How can I find out about clinical trials that might be suitable for me?

Your doctor might ask you if you are interested in taking part in a clinical trial. If they don't and you are interested in taking part in a clinical trial, you can ask your doctor if there is a clinical trial suitable for you. You might be able to be referred to another hospital if there is not a trial running at your hospital. Your medical team won't be offended if you ask about a trial at another hospital.

There are several places you can find information about trials that might be suitable for you:

- Our clinical trials information service, **Lymphoma TrialsLink**, has a regularly updated **database of lymphoma clinical trials and research studies** that are taking place in the UK. You can use it to search for a trial that might be suitable for you. We write a summary of each trial in language that is easy to understand.
- The **Lymphoma Coalition** has a **global database of clinical trials for lymphoma**.

- **National Institute for Health Research (NIHR)** is a government organisation that aims to improve the health and wealth of the nation through research. It has a searchable database of clinical trials at **Be Part of Research**.
- **Cancer Research UK** is a charity that funds research and provides information on all types of cancer. They maintain a **database of clinical trials** taking place in the UK.
- **ClinicalTrials.gov** is a US database of clinical studies that are being conducted around the world, including the UK. It is searchable by country.
- The **World Health Organization** runs an **international clinical trials registry** that you can search by country.

If you find out about a trial that you might be eligible for, discuss it with your doctor. You can print the information you find and show it to them. They can check the eligibility criteria and find out whether you may be suitable.

You might not find a trial that is suitable for you. There are relatively few trials running at any one time and they are only open to new participants for a limited period of time. If you do find a trial studying the type of lymphoma you have, you might not meet all the eligibility criteria. However, new trials are opening all the time. If there is not a trial that is suitable for you at the moment, you may find one at a later date. In the meantime, you will be treated with the best treatment available for you.

Advantages and disadvantages of clinical trials

Before you join a clinical trial, you are given a patient information sheet (PIS) that describes the possible risks and benefits of taking part. However, there is no way of knowing exactly how a treatment will affect you.

The trial team is not allowed to try to persuade you to take part in a clinical trial. They have to give you all the information they have and tell you all the possible disadvantages of participating in the trial. It might feel as though they are trying to talk you out of participating, but you do need to know what the trial could mean for you.

Potential advantages of taking part in a clinical trial

Most of the advantages of taking part in a clinical trial are linked to receiving good medical care. This includes access to expert staff, good quality information and careful follow-up. Clinical trials can also provide you with:

- **Access to expert support and advice about the trial procedures and treatments**: Doctors and nurses following the trial protocol act on the most current information about someone in your situation. You also have access to an experienced research nurse or a clinical nurse specialist with an interest in research. They can explain the trial to you and help you discuss any worries with your medical team.
- **Close monitoring**: Clinical trials pay particular attention to **side effects** (unwanted effects of a medical treatment) and to your response to treatment. You may have more tests than usual to see how you are getting on.
- **Longer follow-up**: You might be followed up for longer than usual because the study team wants to know what happens with your health long-term.
- **Access to the latest treatments**: Many clinical trials provide you with an opportunity to have an experimental treatment that is not available outside the trial. They can also offer access to another treatment when all standard options have been tried.
- **Access to information**: For a trial to be approved, participants have to be given good quality information about the treatment involved and the possible risks and benefits of the trial. You are likely to receive more written information than you would in standard practice. The study team are available to answer your questions.
- **Helping others**: Clinical trials aim to improve the treatment of lymphoma. Thanks to past participants in clinical trials, treatment is now safer and more effective than it used to be. Taking part in a clinical trial may help people with lymphoma in the future, even if the trial doesn't benefit you directly.

Potential disadvantages of taking part in a clinical trial

There are possible risks involved in taking part in a clinical trial. Your doctor or research nurse can discuss any concerns you have to help you decide whether a clinical trial is suitable for you.

Some of the factors you should consider include:

- **Uncertainty about the outcome**: Clinical trials are set up to answer questions. No one knows for sure what will happen. You might be in a treatment group that doesn't do as well as expected, or you might get unexpected side effects. There is more uncertainty in early phase trials, where less is known about the treatment's effects than in later stage trials. Phase 1 trials are usually only open to people with no other treatment options.
- **No choice of treatment**: You and your doctor might not get a choice in what treatment you have. If the trial is blinded, you won't even know what treatment you are having. Sometimes your doctor won't know either. There are some things to remember though:
    - You might be disappointed if you are in the control group (the group that the new treatment is being compared to). However, the control group is given the best standard treatment available and it might be just as good as or even better than the new treatment.
    - If it becomes obvious one group is doing much better than the other, the trial might close early and everyone might switch to the better treatment if possible.
- **Extra hospital visits and tests**: Some people find these reassuring but they could be stressful or inconvenient for you. Discuss the risks of any extra tests with your medical team (for example, extra scans can increase your exposure to radiation). These risks are assessed when the trial is designed, but it is important that you are comfortable with them.
- **Worrying about information you are given**: Taking part in a trial means dealing with a lot of information. Talk to your medical team if anything is troubling you or you find the information difficult to understand.

Remember, you don't have to enter a clinical trial even if your doctor asks you if you would like to. It does not affect your standard of care if you say no.

What happens if I decide to take part?

Consider the information you are given and ask all the **questions** you want to. You do not have to take part in a clinical trial if you don't want to. It is your decision. Turning down an offer to take part in a clinical trial does not influence the standard of care you receive.

If you decide to take part after you have considered everything, you need to sign a consent form. Signing the form gives your informed consent. This means that you understand what is involved in the trial and agree to take part.

You can change your mind at any time during the trial and withdraw from the trial without giving a reason. Signing the consent form doesn't mean you have to continue to take part if you don't want to.

If you decide to withdraw from the trial, you might not be able to continue to have the trial treatment. You'll usually be given the standard treatment for someone in your situation instead. Sometimes, the treatment you have in the trial influences what treatment you can have next. For example, it might not be possible to switch from one **chemotherapy regimen** (combination of drugs) to another. Before you agree to take part in a clinical trial, ask your trial team what might happen if you change your mind and want to withdraw from the trial.

What happens after treatment?

After you finish treatment as part of a trial, there is usually a long period of follow-up, often several years. The trial team is interested in long-term as well as short-term effects of a treatment. As part of follow-up, you attend the hospital regularly for tests and a check-up. Details of what is involved are included on your information sheet.

It can take several years before the results of a clinical trial are available. This is because it takes time to recruit enough people, treat them according to the trial protocol, and follow them up afterwards. Researchers also need to analyse the results to work out what the outcome of the study is. Results are usually reported at major medical conferences and in medical or scientific journals. For some clinical trials, people who took part are sent a results information sheet. For trials listed on our **Lymphoma TrialsLink** database, we provide a summary of results when they are available.

We have separate information about the topics in **bold font**. Please get in touch if you'd like to request copies or if you would like further information about any aspect of lymphoma. Phone 0808 808 5555 or email **information@lymphoma-action.org.uk**.

References

The full list of references for this page is available on our website. Alternatively, email **publications@lymphoma-action.org.uk** or call 01296 619409 if you would like a copy.

Acknowledgements

- With thanks to Susan Neeson, Lymphoma Research Nurse Team Leader, The Christie NHS Foundation Trust, for reviewing this information.
- We would like to thank the members of our Reader Panel who gave their time to review this information.

Content last reviewed: July 2019
Next planned review: July 2022
LYMweb0041ClinicalTrials2019v3

Health & care information you can trust
The Information Standard Certified Member

Tell us what you think and help us to improve our resources for people affected by lymphoma. If you have any feedback, please visit **lymphoma-action.org.uk/Feedback** or email **publications@lymphoma-action.org.uk**.

All our information is available without charge. If you have found it useful and would like to make a donation to support our work you can do so on our website **lymphoma-action.org.uk/Donate**. Our information could not be produced without support from people like you. Thank you.

Disclaimer

We make every effort to make sure that the information we provide is accurate at time of publication, but medical research is constantly changing. Our information is not a substitute for individual medical advice from a trained clinician. If you are concerned about your health, consult your doctor.

Lymphoma Action cannot accept liability for any loss or damage resulting from any inaccuracy in this information or third party information we refer to, including that on third party websites.

Neither the Information Standard scheme operator nor the scheme owner shall have any responsibility whatsoever for costs, losses or direct or indirect damages or costs arising from inaccuracy of information or omissions in the information published on the website on behalf of Lymphoma Action.