

Phases of clinical trials

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What are trial phases?

Clinical trials testing new treatments are divided into different stages, called phases. The earliest phase trials may look at whether a drug is safe or the side effects it causes. Later phase trials aim to test whether a new treatment is better than existing treatments.

There are 3 main phases of clinical trials – phases 1 to 3. Phase 1 trials are the earliest phase trials and phase 3 are later phase trials.

Some trials have an earlier stage called phase 0, and there are some phase 4 trials done after a drug has been licensed.

Some trials are [randomised](#). This means the people taking part are put into one of the treatment groups at random. Doing this means the results are more reliable.

Trial phases at a glance

Phase	Number of people taking part	Cancer type	Main aims of trial	Is it randomised?

0	Small – often about 10 to 20 people	Often lots of cancer types	Testing a low dose of treatment to check it isn't harmful	No
1	Small – often about 20 to 50 people	Often lots of cancer types	Finding the best dose of treatment, what the side effects are and what happens to the treatment in the body	No
2	Medium - tens of people, sometimes over 100	Usually one or two cancer types, sometimes more	Checking the best dose of treatment, finding out more about side effects and looking at how well the treatment works	Sometimes
3	Large - hundreds or thousands of people	Usually one cancer type, sometimes more	Comparing the new treatment to the standard treatment or to a dummy drug	Usually
4	Medium to large, variable	Usually one cancer type, sometimes more	Finding out more about long term benefits and side effects	No

Phase 0 trials

The earliest trials of drugs in people are usually phase 1 trials. But your doctor might ask if you would like to join a phase 0 study. These studies aim to find out if a drug behaves in the way researchers expect it to from their laboratory studies.

Phase 0 studies usually only involve a small number of people and they only have a very small dose of a drug. The dose of the drug is too small to treat your cancer, but you are also less likely to have side effects.

Phase 0 trials aim to find out things such as:

- whether the drug reaches the cancer cells
- what happens to the drug in the body
- how cancer cells in the body respond to the drug

You might have extra scans and give extra samples of blood and cancer tissue (biopsies) to help the researchers work out what is happening.

Phase 1 trial

Phase 1 is sometimes written as phase I. They are usually small trials, recruiting only a few patients. The trial may be open to people with any type of advanced cancer, usually those who have already had all other available treatments.

Phase 1 trials aim to find out:

- how much of the drug is safe to give
- what the side effects are
- what happens to the drug in the body
- if the treatment helps shrink the cancer

Patients are recruited very slowly onto phase 1 trials. So even though they don't recruit many people, they can take a long time to complete.

They are often dose escalation studies. This means that the first few patients that take part have a very small dose of the drug. If all goes well, the next few people have a slightly higher dose. And so on until they find the best dose to give. The researchers monitor the side effects people have and how they feel.

In a phase 1 trial you may have lots of blood tests because the researchers look at how your body copes with and gets rid of the drug. They carefully record any side effects you may have and when you have them.

The main aim of phase 1 trials is to find out about doses and side effects. They need to do this first, before testing the potential new treatment to see if it works. Some people taking part may benefit from the new treatment, but many won't.

Phase 2 trials

Phase 2 is sometimes written as phase II. Not all treatments tested in a phase 1 trial make it to a phase 2 trial.

These trials can be for people who all have the same type of cancer, or for people who have different types of cancer.

Phase 2 trials aim to find out:

- if the new treatment works well enough to be tested in a larger phase 3 trial
- which types of cancer the treatment works for

- more about side effects and how to manage them
- more about the best dose to give

These treatments have been tested in phase 1 trials, but you may still have side effects that the doctors don't know about. Treatments can affect people in different ways. Some people taking part may benefit from the new treatment, but some won't.

Phase 2 trials are usually larger than phase 1. There may be up to 100 or so people taking part. Sometimes in a phase 2 trial, a new treatment is compared with another treatment already in use, or with a dummy drug ([placebo](#)).

Some phase 2 trials are randomised. This means the researchers put the people taking part into treatment groups at random.

You can find out about [randomised trials](#).

Phase 3 trials

Phase 3 is sometimes written as phase III. These trials compare new treatments with the best currently available treatment (the standard treatment).

Phase 3 trials aim to find out:

- which treatment works better for a particular type of cancer
- more about the side effects
- how the treatment affects people's quality of life

They may compare standard treatment with:

- a completely new treatment
- different doses of the same treatment
- having the same treatment more, or less, often
- a new way of giving a standard treatment (radiotherapy for example)

Phase 3 trials usually involve many more patients than phase 1 or 2. This is because differences in success rates may be small. So, the trial needs many patients to be able to show the difference.

Sometimes phase 3 trials involve thousands of people in many different hospitals and even different countries. Most phase 3 trials are randomised. This means the people taking part are put into treatment groups at random. See our information about [randomised trials](#).

Phase 4 trials

Phase 4 is sometimes written as phase IV. These trials are done after a drug has been shown to work and has been licenced.

Phase 4 trials aim to find out:

- more about the side effects including the rarer side effects and safety of the drug
- what the long term risks and benefits are
- how well the drug works when it's used more widely for people not included in the phase 3 trial

We have information about [how drugs are licensed](#).

Trials covering more than one phase

Most trials are just one phase. But some trials cover more than one phase. For example, the same trial can include both phase 1 and phase 2. So you may see trials written as phase 1/2 or phase 2/3.

References

Oxford Handbook of Clinical and Healthcare Research (1st edition)

R Sumantra, S Fitzpatrick, R Golubic and others

Oxford University Press, 2016

Related information

You can read our information about:

[What trials are](#)

[Randomised trials](#)

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