

# Factsheet Thinking about joining a clinical trial?

## Key points

- Before you make a decision about joining a clinical trial, make sure you fully understand what's involved.
- There will be benefits and risks to joining any clinical trial.
- Discuss the decision with your doctor and ask questions to find out what the trial would mean for you.



People decide to take part in clinical trials for different reasons. It is something that is best decided in close consultation with your [healthcare team](#).

It is worth taking plenty of time to think carefully about your treatment options, and to ask questions before deciding.

If you are ill and a doctor recommends an experimental drug as the best treatment, or offers a new drug as part of a comparative trial, you may have to decide whether or not to take part in the trial at quite short notice. Your doctor should explain to you what the alternatives are, and the benefits and risks of joining or not joining the trial.

You can find out more about clinical trials in our factsheet [Clinical trials](#).

## Joining a trial

It is a good idea to consider your motivation for taking part in a trial, and what you will need to take into account.

- Can you commit to taking the treatment as required?
- Can you commit to attending all the appointments involved?
- Do you have support from friends or family if needed?

- Do you agree with the trial's design and requirements?

Some reasons for **joining a trial**:

- You might have access to new drugs, or to new forms of treatment, which may be more effective than existing ones.
- You might receive more frequent [health monitoring](#) and have access to more advanced tests.
- The findings of the research may benefit other people with HIV.

Some reasons for **not joining a trial**:

- You are concerned about being on a treatment where the outcome or effectiveness is not yet known.
- It would involve too many hospital or clinic appointments for you.
- The [pill-taking timetable](#), or restrictions on your daily life, don't feel manageable.
- You are worried about possible unknown [side-effects](#).
- You are pregnant, or want to be, or don't want to use the form of [contraception](#) required by the study.

## Some questions to ask before joining a trial

**How will I take the treatment being trialled?** You may want to ask how the treatment is given and how often, [how it needs to be taken](#), and how it will be provided.

**How often will I have to visit the clinic?** Make sure that the schedule for clinic visits is explained to you so you can make a realistic decision. Ask whether the trial is able to offer financial help with expenses you might have such as childcare and transport costs.

**What will happen at these visits?** Trial monitoring visits will normally include blood tests, seeing a doctor, and an opportunity to report any side-effects or problems you are having. Occasionally, a study may require [other tests](#) such as scans, ultrasounds, or, on rare occasions, biopsy.

**When will I get the results of blood tests?** Some trials will give you the results of [viral load](#) tests and [CD4 counts](#) right away, allowing you to discuss options with your doctor if your viral load is not suppressed. However, in other studies your doctor will decide when you should come off the trial medication if you show signs of a poor response to your current treatment.

**What other medications or drugs can I take while on this trial?** The trial protocol will usually specify certain drugs that should not be taken in case they confuse the outcomes of the trial. Ask for a full list of drugs (including over-the-counter medicines for hay fever, headache or other everyday complaints, or recreational drugs) that should be avoided.

**Are there any restrictions relating to contraception or pregnancy?** Many trials require women who could become pregnant to be using [contraception](#). Most trials exclude pregnant and

breastfeeding women. Find out what you would have to do if you thought that you had become pregnant while in the trial, and what is known about the potential effects of the study medication on the unborn child.

**What happens if my condition worsens?** Many trials require you to leave the trial if your condition worsens beyond a certain point. Some trials guarantee that people who have been receiving a placebo will be switched over to receive the genuine trial drug if their condition deteriorates.

**How long will the study last and how long will I have to take part for?** Trials can last any length of time from a few weeks to years.

**How will this trial affect my future treatment options?** Finding out how [resistance](#) to a new anti-HIV drug develops is an important part of an HIV treatment trial. Clear safeguards should be built into the design of the trial to minimise the risk that you will develop drug resistance.

**How will I be informed of the trial's results when it ends?** The researchers have a duty to report on the results of the trial, whatever they show, and how they contribute to existing knowledge.

**How will other drugs taken during the trial be chosen?** Unless the trial is specifically designed to recruit only those people who have taken particular drugs in the past, you should be offered the other HIV drugs you take alongside the trial drug in the way now considered to be the standard of care – by [resistance testing](#).

Other questions you might want to ask could include:

- What is the aim of the trial and how will it help people?
- Who is funding the trial?
- Would I need to make any lifestyle changes to take part?
- What is already known about the possible risks and benefits of the trial treatment?
- What are the possible side-effects of the treatment?
- Is there support available for me or my family while I am taking part?
- What happens if I stop taking the trial drug or leave the trial early?
- Who can I contact if there is a problem and when are they available?

## Primary infection and chronic infection studies

Trials which recruit people with no previous treatment experience fall into two categories:

- [Primary infection](#) (people who acquired HIV within the past six months).
- [Chronic infection](#) (people who have been living with HIV for longer).

**If you are asked to join a primary infection study, consider whether you are ready to commit to a clinical trial at a time when you may still be adjusting to living with HIV, for example getting used to knowing about your HIV status and building a relationship with your clinic.**

But if you do join one of these studies, you will be helping to answer very important questions.

Joining a trial after you have been living with HIV for a number of years will have different implications, depending on how long you have known that you are living with HIV, and your overall state of health.

## For more information

You can find more information on clinical trials, and on making the decision whether or not to join one, on the following websites:

- NHS Choices: [www.nhs.uk/Conditions/Clinical-trials](http://www.nhs.uk/Conditions/Clinical-trials)
- UK Clinical Research Collaboration: [www.ukcrc.org](http://www.ukcrc.org) and in the booklet *Understanding clinical trials* (PDF)
- UK Clinical Trials Gateway: [www.ukctg.nihr.ac.uk/home](http://www.ukctg.nihr.ac.uk/home)

### Find out more

**Clinical trials** Simple factsheet

**Anti-HIV drugs** Information booklet

**Talking points** Online, interactive tool