

# Thinking about joining a clinical trial?

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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. Generally, 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 alternative is, and the benefits and risks of joining or not joining the trial.

## Reasons to join 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 monitoring and have access to more advanced tests.
- The findings of the research may benefit other people with HIV.

## Reasons not to join 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.

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 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 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 birth control 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?** 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 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.

**Would I be advised to start treatment now even if this trial wasn't taking place?** Trials which recruit people with no previous treatment experience fall into two categories:

- Primary infection (people infected within the past six months).
- Chronic infection (people who have been infected for longer).

If you are asked to join a primary infection study, you might want to think about whether you are ready to commit to long-term treatment at a time when you may still be adjusting to living with HIV. But if you join one of these studies, you will be helping to answer very important questions.

Joining a trial after you have been HIV-positive for a number of years will have different implications, depending on how long you have known that you are HIV-positive, and your overall state of health. If you have been diagnosed recently, you may also be getting used to knowing about your HIV status and building a relationship with your clinic.

Other questions you might want to ask could include:

- 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?
- 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?

You can find out more from NAM's *Clinical trials* factsheet, on the NHS Choices website: [www.nhs.uk/conditions/clinical-trials](http://www.nhs.uk/conditions/clinical-trials) and from the UK Clinical Research Collaboration: [www.ukcrc.org](http://www.ukcrc.org), and about trials looking at HIV treatment and prevention in *HIV and clinical trials*.