

clinical trials

Advances in HIV medicine have only been possible because of clinical trials. These are essential to show the potential benefits of a treatment as well as its possible risks. This factsheet provides a brief introduction to the types of clinical trials you might be invited to join, to how trials are structured and to your rights and responsibilities whilst on a trial.

What aspects of HIV are examined in clinical trials?

Clinical trials for people with HIV are currently testing treatments in five broad areas.

- Treatment to attack HIV to stop or delay it damaging the immune system.
- Treatment to boost the immune system.
- Treatment to fight infections which frequently occur in people with HIV.
- Treatment to prevent infections developing in people with HIV – often called prophylaxis.
- Vaccines to stimulate a response to HIV or other infections.

Structure of clinical trials

A new treatment will initially undergo rigorous testing in the laboratory and animal studies before the clinical trial process in humans begins. Trials then have a number of stages – or phases – in humans depending on how far advanced research into the drug is.

- Phase I: Only a small number of people are involved at this stage which is to see if the drug being tested is safe in humans and what the maximum safe dose is.
- Phase I/II: This stage is to see what the maximum safe dose of a drug is.
- Phase II: This stage looks at the effect of a drug in the short-term, normally six months.
- Phase III: This stage normally lasts for at least a year and often compares the new drug with a treatment already in use or with an inactive substitute called a placebo.

If a trial is comparing two treatments they are usually randomised. This involves assigning people to take a particular treatment. Randomisation is important to ensure that people in different arms of the study are broadly similar.

Many clinical trials are also 'blinded.' If it is 'double blinded' it means that neither you nor your doctor knows what treatment you are taking.

If it is 'single blinded' it means that you do not know what treatment you are taking. This is to ensure that nobody's expectations affect the outcome of a study.

The most common type of clinical trials is a comparison study. In these studies, one group of people will receive a new treatment, the other the current standard of care.

If there is no current treatment, the usual type of study is a placebo controlled trial. This compares the new treatment with a dummy pill – a placebo. People do not know whether they are taking the new treatment or the placebo.

Other studies may simply compare different doses of drugs. These may or may not be blinded.

There are also 'open label' studies. In these trials both you and your doctor will know what treatment you have been given.

Before a trial starts

All clinical trials have a protocol. This sets out the objectives and procedures for the trial, including who is eligible for recruitment, what the treatment is, and what participation in the trial will involve. The protocol has to be approved by an ethics committee before it can start.

Trials have inclusion criteria – rules about who can join, and exclusion criteria – rules about who cannot join. These differ from trial to trial, but generally pregnant women cannot participate in clinical trials.

Before you sign-up to a trial you have to give your written consent. You should only give this once all the important facts about the trial have been explained to you and when you understand them.

Don't rush into joining a clinical trial. You should be given written information about the study. Read it carefully and don't be frightened to ask questions.

Rights and responsibilities

You should not be pressured into joining a trial. Saying no should not affect the standard of care you receive from your clinic. If you join a trial, you can withdraw at anytime without having to give a reason. You should be given details of how to contact somebody out of normal clinic hours or if there is an emergency.

If you join a trial, you also have responsibilities. You should follow the rules of the trial as closely as possible, for example by taking your medication as directed and attending your appointments. Tell your doctor if you experience any changes in your health or experience any unusual symptoms – even if it is just a headache or rash.

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**for details write to NAM
Freepost LON 17995
London SW9 6BR**

tel
+44 (0) 20 7840 0050
web
www.aidsmap.com