Factsheet Clinical trials

Key points

- A clinical trial is a study in which a new treatment is assessed.
- There are legal requirements on how a trial should be run.
- If you choose to join a trial, you will have certain rights and responsibilities.

This factsheet provides a brief introduction to the types of clinical trial that people living with HIV might be asked to join. There is also information on how a trial is organised and what your rights and responsibilities are if you join a trial.

You can find out more about joining a clinical trial in our factsheet *Thinking about joining a clinical trial?*

What is a clinical trial?

A clinical trial is a research study, where a new drug or treatment is tested to assess its benefits and risks. A trial will try to find out:

- if the treatment is safe
- if the treatment has any side-effects
- if the new treatment is better than any existing treatments.

People may choose to take part in clinical trials because the research helps doctors understand more about a condition or treatment, because they want to take an active role in their own health care or because they may be one of the first people to benefit from a new treatment.

Who runs clinical trials?

In the UK, research and clinical trials are often part of the NHS's work, involving doctors and other health professionals. This research will often take place in hospitals or clinics.

Research also takes place in universities and research institutes, in social care services, and in the private sector (e.g. trials run by a pharmaceutical company).

How are trials regulated?

There are legal requirements on how a trial should be run. The Medicines and Healthcare products Regulatory Agency (MHRA) reviews every trial before it starts.

The detailed plan for a trial (the 'protocol') lays down procedures, aims and objectives for the trial. This includes how treatment will be given, who is eligible (known as inclusion and exclusion criteria), the length of the study and how results will be assessed.

An ethics committee must approve the protocol. Ethics committees are responsible for protecting the rights and interests of people in the trial. Until approval, researchers cannot recruit any participants.

Clinical trial phases

A new treatment is first tested in the laboratory. If the results from these tests are promising, clinical trials are started with people. There are a number of stages, or phases.

- **Phase I:** This stage is to see how a drug works in the body and what the right dose might be. The drug is only given to a small number of people in this phase.
- **Phase II:** This stage looks at the effectiveness of a drug in the short term, normally about six months, and is given to a larger group of people.
- **Phase III:** This stage compares the new drug to an existing treatment or a dummy treatment called a placebo. It involves an even larger group of people and normally lasts at least a year.
- **Phase IV:** This final stage is carried out on drugs that have been approved and licensed and looks at the long-term effects of the drug.

Types of trials

Comparison studies: In these studies, one group of people will receive a new treatment, the other group will be given the treatment that is in current use.

Randomised trials: If a trial is comparing two treatments it is normally randomised. This means that people are selected at random, usually by a computer, to ensure that treatments are being tested in people who have similar characteristics.

Placebo-controlled trials: If there is no current treatment, the study will be a placebo-controlled trial. This compares the safety and effectiveness of the new treatment to a placebo. If

you take part in this kind of study, you won't know if you are taking the active treatment or the placebo.

Blinded trials: Many trials are 'blinded'. This is to make sure that your or your doctor's expectations don't influence the results of the study. If a study is 'double blinded' it means that neither you nor your doctor knows which treatment you are taking. If it is 'single blinded' it means that you do not know which treatment you are taking, but your doctor does. In an 'open label' study, both you and your doctor know what treatment is being given.

Dose studies: Some trials compare different doses of drugs. Sometimes these studies are blinded.

Non-treatment studies: A lot of research is conducted in HIV clinics that doesn't provide access to any new treatment. This research is often called 'observational'. A sample of clinic patients is recruited, aiming to make this group representative of people who use the clinic. These studies help doctors gain a better understanding of important issues related to HIV treatment and care, or life with HIV. The study may simply involve looking at your medical records, but it could involve other elements, such as some tests. Participation is always voluntary.

Trial information

You should always be given written information about a trial. You should read it carefully and ask questions if there is anything you don't understand.

Before you join a trial you have to give your written consent (called informed consent). You should only give this after the trial has been explained, including the possible risks and benefits of taking part. You should not have pressure put on you to join a trial. Saying no to joining a trial should not affect the standard of care you receive.

Rights and responsibilities

You have both rights and responsibilities if you join a trial.

If you are considering joining a trial, there are a number of issues you may want to consider. You can find a list of questions you may want to ask in our factsheet *Thinking of joining a clinical trial?*

If you do join a trial, you can withdraw at any time without having to give a reason.

You should be given details of how to contact somebody if there is an emergency.

"In the UK, research and clinical trials are often part of the NHS's work."

You also have responsibilities if you join a trial. For example, you will need to take your treatment as instructed and to keep any appointments. It's also important to tell your doctor if you experience any changes in your health or develop any symptoms.

What happens after the trial?

After the trial has finished, the results will be available to anyone who has taken part in it. The results will often also be published.

If you have been taking a new treatment as part of the trial, it may not always be possible to continue taking it once the trial has ended. It may also take a while for the drug to become available through the NHS. However, sometimes you may be able to buy the treatment.

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
- UK Clinical Research Collaboration: www.ukcrc.org and in the booklet *Understanding clinical trials*
- UK Clinical Trials Gateway: www.ukctg.nihr.ac.uk

Find out more

Thinking about joining a clinical trial? Simple factsheet

Anti-HIV drugs Information booklet

Talking points Online, interactive tool

nam aidsmap
Sharing knowledge, changing lives

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