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clinical trials

fifth edition 2008



acknowledgements

Edited by Michael Carter **Fifth edition 2008**

Due for review in 2010

NAM is a charity that publishes information for people affected by HIV and those working with them. We believe information helps people to make decisions about, and be in control of, their lives, health and treatment options.

Awards

The 1999 edition of this booklet received first prize in the BMA Medical Book Competition. The 2003 edition was commended in the BMA Medical Book Competition.

Thanks for the assistance of

Professor Janet Darbyshire
Medical Research Council, London

Dr Philippa Easterbrook
Chelsea and Westminster
Hospital, London

Dr Martin Fisher
Royal Sussex County Hospital,
Brighton

Dr Graeme Moyle
Chelsea and Westminster
Hospital, London

Maxine Troop
Chelsea and Westminster
Hospital, London

Dr Mike Youle
Royal Free Hospital, London

Funders

NAM is grateful to the funders of this booklet series:

Department of Health,
Healthsure Charitable Trust and
NHS London HIV & GUM
Commissioning Consortium.



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clinical trials

This booklet answers the questions that people with HIV often ask about clinical trials. It is meant to help you decide whether or not to take part in a particular study, and to help you in discussions with doctors and trial nurses before, and during, the trial. A glossary of some of the words and phrases used in trial information is on page 33.

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What is a clinical trial?

1

Almost every month we learn about a new drug or some other treatment for HIV infection from television or newspapers. However, 'treatment breakthroughs' reported in the media are often exaggerated and premature.

Any new treatment, no matter how promising it appears to be in laboratory tests, has to go through a careful process of clinical trials in people before its usefulness can really be known.

A clinical trial is a research study used to assess the benefits and risks of a new treatment. It is now widely agreed that a properly conducted clinical trial is the only way to prove that a treatment is effective.

Major advances in HIV therapy have been the result of clinical trials.

For example

- The Delta study showed that dual combination therapy with AZT/ddI or AZT/ddC prolonged life and delayed the onset of AIDS compared with AZT alone.
- The ACTG 320 study showed that triple therapy with AZT/3TC/indinavir was more likely to prolong life and reduce symptoms than AZT/3TC among people with CD4 counts below 200.

- The ACTG 076 study showed that AZT treatment during pregnancy, labour and the infant's first weeks of life can reduce the risk of HIV transmission from mother to child by two-thirds.
- The 006 study showed that a combination of the non-nucleoside efavirenz with AZT/3TC was superior to indinavir, AZT and 3TC over three years in terms of the percentage of people maintaining viral suppression.
- The MS98-896 study showed that lopinavir boosted by a small amount of ritonavir achieved more durable suppression of HIV than unboosted nelfinavir.
- The APRICOT study showed that treatment with a combination of pegylated interferon and ribavirin was the best option for hepatitis C virus infection in HIV-positive people.
- The SMART study showed that people who took CD4-guided treatment interruptions were more likely to develop HIV-related illness and some other illnesses than people who took their HIV treatment continuously.

What sort of trials are carried out in HIV infection?

3

Clinical trials for people with HIV are currently testing treatments in six broad categories, at all stages of HIV disease. Some new trials are testing combinations of these approaches:

- Treatments intended to attack HIV at different stages of its lifecycle in order to stop or delay it damaging the immune system, such as protease inhibitors, non-nucleoside reverse transcriptase inhibitors (NNRTIs) or entry and integrase inhibitors in combination with other antiretroviral drugs.
- Treatments intended to improve the immune system (immunomodulators), such as interleukin-2.
- Treatments for side-effects, such as lipodystrophy.
- Treatments for other infections often seen in people with HIV such as hepatitis B virus or hepatitis C virus.
- Screening and treatment for sexually transmitted infections and anal and cervical cancer.
- Vaccines intended to stimulate an immune response to HIV or other infections.

4 What types of trials might I be asked to join?

Clinical trials begin only after preliminary studies in the laboratory, as well as with animals, have shown that the drug is safe enough to be taken by people. Clinical trials in people are usually conducted in three steps or phases:

Phase I

Phase I trials test the treatment in only a few people (usually healthy volunteers who are not HIV-positive or those with HIV who are not on other medications) to learn whether it is safe to take, and to find the maximum safe dose. If you enrol in a phase I trial you may have to spend some time in hospital for close monitoring of drug levels in your blood. There are usually no direct health benefits from participating in a Phase I trial.

Phase I/II

Phase I/II trials test the treatment in up to few hundred HIV-positive people to find the most effective dose.

Phase II

Phase II studies assess whether the treatment is active against the disease in the short term by looking for changes in viral load and CD4 count. If the treatment is not active, no more trials will take place. Phase II trials usually last for at least six months. If you enrol in a Phase II study you will need to attend the clinic on a regular basis for blood tests and other monitoring.

Phase III

Phase III trials test the treatment in a larger group of people, often at many different clinics or hospitals. Usually the drug is given in a dose that has been found to be safe enough for most people in Phase I or II trials, and is thought to be active against the disease. These trials compare the new treatment either with a treatment already in use or, occasionally, with an inactive look-alike pill called a placebo.

Phase III trials usually last for at least twelve months, and also require a commitment to regular clinic attendance.

6 The different methods of comparing treatments

The tested treatment may be an entirely new drug added to existing combinations. Or it could be a new way of using existing drugs, such as comparing once-daily dosing versus twice-daily dosing.

Randomisation

This is an essential feature of almost all clinical trials. Everyone who joins the trial will be assigned to one of the treatment groups at random, usually by computer. This is the best way to make sure that people in different arms of the trial are broadly similar, so that reliable comparisons can be made between the effects of the treatments used in the different trial arms.

Blinded studies

In some trials, neither the researchers nor the participants are supposed to know who is getting the drug and who is getting the standard treatment or no treatment (The medications are all 'packaged' to look the same). This is called a double-blind trial (because both researcher and participant are said to be 'blind' to who is receiving what). When only the participants do not know which treatments they are receiving, but the researchers do, then the clinical trial is known as single-blind. The purpose of blinding is to make sure that nobody's expectations affect the results of the trial. A doctor who knows which patients

were getting a particular treatment might unconsciously assess or treat them in a different way. Similarly, participants who know their treatment might describe their symptoms differently, or they might choose to drop out.

Comparison trial

The most common type of clinical trial is a comparison trial. This is a trial in which one group of people who receive a new treatment is compared with another group of people who receive an existing or standard therapy. When there is a recognised standard treatment for a particular condition, then trials will be designed to compare an experimental

drug with that standard treatment. In this case it would be unethical to give some trial participants no treatment rather than the standard treatment.

Placebo-controlled trials

Where no standard treatment exists for a disease, a trial may compare a new treatment with a dummy drug called a placebo. None of the participants will know whether they are receiving the new drug or the placebo.

Dose comparison trial

Other comparison trials may simply compare different doses of the same drug.

Open-label or uncontrolled studies

Trials in which treatment allocation is not blinded are also called 'open label'. This means that everyone in the trial, and their doctors, know exactly which treatments they are taking. Some studies will evaluate the effectiveness and safety of a new drug without a control group. This means that everyone who enters the study receives the study medication.

The preparation for a trial

The detailed plan for a trial is called a protocol. It lays down procedures for how the treatment will be given, who is eligible to take part, the timetable for tests and visits for participants, the length of the study, how the results will be assessed and so on.

The protocol is written by a group of doctors or other researchers, or by a pharmaceutical company. First, the trial planners will examine previous research on a particular experimental treatment. They then work out the remaining unanswered questions, and design a new trial to try to find out the answers.

Before a study can begin, an ethics committee responsible for each clinic that wants to run the trial must approve the protocol. The members of the ethics committee may vary, but usually include doctors, nurses, at least one lay person and often a lawyer or chaplain. They are responsible for protecting the rights and interests of the people in the trial, and work independently of those running or financing the trial.

It is very important that any clinical trial should be run with the approval of an ethics committee. Such an approval is a good indication that a trial is ethically sound, even though the committee does not monitor the day-to-day running of the trial.

Recruiting participants

The next step is to recruit participants and start the trial. The more quickly participants are recruited to the trial, the sooner it can be completed and the treatment's benefits and risks can be assessed. The difference between the effect of a new drug and another treatment could be small. The drug may have to be tested in a large number of people to get a clear picture of whether it is better, as good as, or worse than other treatments that are currently available.

So, a clinical trial may be seen as a partnership between researchers and people with HIV. Researchers need people

to join their trials so that they can improve medical knowledge about HIV infection. People with HIV may want to help this research, but will also want to make sure that their individual interests are being looked after in the trial.

Researchers want people to join their trials because they share the researchers' uncertainties about which of the options being tested in the trial is the best. This is known as the 'uncertainty principle'.

Who can join a trial?

Each clinical trial has its own rules about who can and who cannot take

part. These are known as inclusion and exclusion criteria, or eligibility criteria.

The inclusion criteria spell out the characteristics that will allow a person into the study. This is to make sure that the people in the trial are similar enough so that it will be clear which groups of people might benefit most from the new treatment. Trials of new treatments are usually run in several different groups of people at once in order to build up a bigger picture of the way drugs should be used best.

For example, a particular trial might aim to test the effect of a drug for people who are at a particular stage of

HIV disease. So a typical inclusion criterion might state that participants in a trial have to have a CD4 (T-cell) count between, say, 200 and 350, or a viral load above 10,000.

The exclusion criteria are intended to protect the trial participants. For example, you may be excluded from a trial if there is a risk of a dangerous interaction between the trial drug and other treatments that you use. A common exclusion criterion forbids trial participants from taking other drugs at the same time which are similar to the one being studied. For example, people in a trial of an anti-fungal drug will not

be allowed to take other anti-fungal drugs while they are on the trial.

Trials sometimes exclude whole groups of people. Most trials exclude pregnant women, because of a fear that the treatment might harm the unborn baby. They also exclude women who are breastfeeding because the drug might be passed onto the child through breast milk. Most trials insist that women are using contraception.

These attitudes are starting to change as doctors realise that everyone should be given the opportunity to take part in trials. It is important to know whether drugs are also safe and effective for

women and drug users, as well as everyone else. This need has to be balanced against the researchers' legal and ethical obligation to ensure that the foetus is safe.

The right time to join a trial

There is no right or wrong time to join a trial. People join trials at different times and for different reasons. Some people are not able to join trials because of particular inclusion and exclusion criteria. Some people choose never to join a trial, and there is nothing wrong with saying no. It is something that is best decided in close consultation with your doctor or nurse.

If you are ill and a doctor recommends an experimental drug as the best chance of 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. But otherwise, it is worth taking plenty of time to think carefully about your treatment options before deciding whether joining a trial is the best option for you.

Informed consent means that before you can join a trial, the researchers must fully explain the study to you and obtain your agreement to take part. The researchers must explain a number of important things about the trial, such as its purpose, the treatment that will be tested, the number of clinic visits, possible benefits and harms, and so on.

A Patient Information Sheet will normally be provided explaining all these things.

Informed consent takes place after all of the important facts about the trial have been explained, when you say that you understand these facts and you agree to enter the trial.

In the case of children, a parent or guardian has to give consent for them to take part in a trial, although older children should also understand and agree themselves.

You will usually be asked to sign a consent form, to show that you understand what has been explained to you. It is meant to show that you have made your decision not only of your own free will, but also in full possession of the facts. You are fully entitled to change your mind after you have signed this form.

If you hear of or read about a trial that interests you, the first step is to talk to the trial's contact person. It does not necessarily matter if you are currently receiving treatment at a different clinic, although you should be sure to tell your regular doctor if you do join a trial at a different centre.

The staff at the trial centre will usually ask you some questions to check that you meet the basic entry requirements for the trial, and you may have a physical examination and a blood test. After the results of all the tests are available, the trial staff will let you know whether or not you are eligible to take part.

During a trial

During a clinical trial you have to follow a timetable of treatment, check-ups and blood tests, to see if the treatment is working. The researchers will keep a careful record of your progress.

You may have to go to the clinic for check-ups as rarely as once every six months or as often as five times a week. In some trials these check-ups may be included in your usual appointments. Usually you can take the trial drug at home, but some trials require you to stay in hospital.

You may have to make some changes to your everyday life. These may include

avoiding certain foods or over-the-counter medicines like antihistamines because they might interfere with the trial drug's action, or taking the treatment before or after meals.

There may also be interactions with alcohol and tobacco, and with recreational drugs such as ecstasy.

You may also be asked to keep a list of any side-effects you notice from the treatment, or a record of your daily activities, or what you eat.

Reasons to join a trial

- Access to new drugs.
- Because you can't decide what to take.
- More frequent monitoring.
- You will see the same doctor or nurse each time.
- Access to the most advanced tests.
- In order to benefit others.

Reasons not to join a trial

- Because you know what treatment you want.
- You don't want to get a placebo.
- Too many hospital visits.
- You can't stick to the pill-taking timetable.
- Anxieties about unknown side-effects.
- You are pregnant, or want to be, or don't want to use the form of contraception laid down by the study.

How often will I have to visit the clinic?

Some trials will require frequent clinic visits, especially during the first few weeks. It is essential for the smooth running of the trial and the accuracy of the trial results that you are able to attend on the days and at the times you are asked to. Make sure that the schedule for clinic visits is explained to you, and if you think it isn't going to be manageable, explain this to your doctor or the trial nurse.

Some clinics or trials are able to offer financial help with childcare and transport costs. Ask whether these are available for the trial you are thinking of joining.

What will happen at these visits?

Trial monitoring visits will normally include taking blood for viral load tests, CD4 counts and other tests intended to monitor the effectiveness and safety of your treatment. You will also see your doctor, and have the opportunity to report any side-effects or problems you are having with taking the medicine. It is especially important to report problems of this sort, because the information you can provide during the trial will help people who take the drug in the future.

Occasionally, a study may require a test such as a bronchoscopy or endoscopy (insertion of an optical tube down the throat and into the lungs or digestive tract), or a lymph tissue biopsy (removal of a microscopic portion of tissue from the lymph nodes or tonsils), or a lumbar puncture (insertion of a needle into the spine to withdraw spinal fluid). These investigations are rare, but ask at the beginning of the study whether any special procedures will have to be carried out at any time.

When will I get the results of blood tests?

Some trial protocols will permit you to receive the results of viral load tests and CD4 counts in 'real time' – within a few days or weeks of the test. This will allow you to discuss options with your doctor if your viral load appears to be increasing, or has not been suppressed satisfactorily.

However, other studies will not provide this information to patients. It will be left up to your doctor to decide when you should come off the trial medication if you show signs of a poor response to your current treatment. It's up to you to decide whether you want to take part in this kind of trial.

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. To be ethical, trials must allow participants to receive the current standard of care. However, many drugs used in HIV therapy have interactions with other drugs. In the case of experimental drugs, ask what is already known about interactions. Ask for a full list of the medicines (including over-the-counter medicines for hay fever, headache or other everyday complaints) which should be avoided.

Many trials also exclude current injecting drug users. This is partly because researchers fear that people who inject drugs will not adhere to the study medication. It is also because there is a risk that opiates, amphetamines, barbiturates, cocaine or impurities in injectable forms of these drugs may lead to harmful interactions with the study medication.

Are there any restrictions relating to birth control or pregnancy?

Many trials require women to use contraception. However, some may not allow the use of the contraceptive pill in

case there is an interaction with the study medication. Find out what sort of contraception is allowed or required. 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 pre-defined point. For example, if your viral load does not fall below the limit of

detection after 24 weeks on the drug, or if your viral load rises above the limit of detection after being undetectable, you may have to come off the trial. 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. Check what the procedure would be in your study.

How long will the study last?

In the protocol, the researchers usually give an estimate of how long the trial will last. While some trials last only a few weeks, others can go on for years. In many large trials, a special group of

independent experts and lay people, called a Data and Safety Monitoring Committee, checks regularly on the results of the trial while it is taking place. If they find that one group of patients is doing much better than the other, they can recommend that the trial is stopped earlier than planned so that the better treatment can be offered to all the participants. They can also recommend that a trial should be stopped if many trial participants develop serious side-effects.

Some trials collect information on the participants' health even after the trial has stopped. If the results are favourable, some trials will offer a

supply of the drug to all participants in the study until it becomes available through other access programmes or is licensed for doctors to prescribe.

How will this trial affect my future options?

One of the most important things that may be studied in a trial is how resistance to the trial drug develops. Developing drug resistance is one of the risks of participating in a clinical trial, but it is a potential risk of many forms of antiretroviral treatment. Clear safeguards should be built into the design of the trial to minimise the risk that you will develop resistance.

These safeguards are based on current knowledge about the best ways to avoid resistance. For example, your treatment may be changed if your viral load increases above the limit of detection after a period of suppression.

Participation in a trial of one drug can also affect your opportunity to join future trials, whether or not you develop resistance to the drug. This is because it is often preferable to test new drugs in people who have absolutely no risk of cross-resistance, in order to get clear results. So if you have previously taken a protease inhibitor, you may be excluded from a future protease inhibitor trial because the researchers want to test the

drug in protease inhibitor 'naive' people – those people who have never taken one.

Will I be informed of the trial's results when it ends?

Sadly, many researchers and drug companies have not been good at communicating trial results to the people who took part. Many people may find it unacceptable that they are not informed of the practical outcome of their time in the trial, or only stumble across the results by chance in (often distorted) newspaper accounts. Ask how the researchers will ensure that you are told about the trial results.

If for any reason you don't approve of the trial design, it is important to tell the researchers. For instance, if you believe that joining the trial is the only way of getting an experimental treatment, you may decide that your interests are best served by joining the trial even though you are unable or unwilling to comply too closely with the rules. However, the researchers may be able to suggest other options if you are frank with them.

How will other drugs taken during the trial be chosen?

An increasing number of trials are aimed at people who already have experience of previous anti-HIV

treatment, and these people may have resistance to some drugs. Unless the trial is specifically designed to recruit only those people who have taken particular drugs in the past, you should be offered the opportunity to choose the drugs you take alongside the trial drug in the way now considered to be the standard of care – by resistance testing.

Resistance tests are now recommended in the UK for people newly diagnosed with HIV, people who are about to start their first HIV treatment combination, and people who are changing treatment. Every clinical trial into an experimental HIV drug should therefore offer resistance tests.

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:

- Those for people infected within the past six months (primary infection).
- Those for people who have been infected for several years (chronic infection).

If you are asked to join a primary infection study, you should think carefully about whether you want the commitment of long-term treatment at a time when you are still adjusting to living with HIV.

Beginning treatment during primary infection means that you would be starting treatment 5-7 years before current thinking suggests you need it. Trials are trying to answer questions like: Will a short period of treatment just after infection influence the long term course of HIV infection? Is it better to continue that treatment indefinitely, or should it be stopped after a year or two?

At the moment the answers to these questions are unknown, and that is why clinical trials are taking place. If you join one of these studies, you will be helping to answer some 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. It may be very difficult to deal with taking part in a study if you have been recently diagnosed, because you are still getting used to knowing about your HIV status and building a relationship with your clinic. You should not be made to feel that you are expected to join a study just because your doctor has suggested that you might consider it.

There is also a danger that you may be encouraged to start treatment earlier

than might be necessary, and you end up taking medication for longer than if you had decided to wait.

Do not rush into a decision about joining a trial. Take time to consider all your options and all the pros and cons. Make sure that you have had time to consider how the trial might affect you. Make sure you have had a chance to discuss all your questions or concerns with the doctor.

It is sensible to adopt a sceptical attitude if you are ever told that a clinical trial has no possible drawbacks or hazards: this is rarely true about any treatment. After all, if we knew that a drug was completely safe and effective, there would not be any need for the trial.

Written information, which you can take away and read at leisure, should be

provided. If a trial is already under way, ask if it is possible to meet or talk to someone who has already taken the drug.

There is nothing wrong in saying 'no' or asking for more time to think about your decision.

It may be helpful to think about how you reached a decision on an important or complicated question in the past. Perhaps you could talk through the issues with a friend, who may help you to clarify your own views. Or you might find it useful to talk to someone on a telephone helpline; such as those given at the back of this booklet.

28 Rights and responsibilities

If you join a trial, you have certain responsibilities to the trial researchers. The researchers should also respect certain rights that you have.

Your rights when you join a trial

First and foremost, no-one should force you or pressure you into entering a trial. It is a choice that you alone can make after you have received and understood all the facts about the study. You have the right to get clear answers to any questions that you may have before you agree to enrol.

Once you have entered the trial you have the right to withdraw from it at any time without this affecting the regular medical care you receive. You do not have to give any reason.

Feel free to ask about the results of any tests that you have to take during the trial. You will probably want to keep track of your progress in the trial to help you decide whether to continue in the trial or not. But bear in mind that many trials are double-blinded, meaning that neither you nor your doctor knows which arm of the trial you are in. So even your doctor may not be told the results of some of the tests performed upon you.

Finally, you should always be able to contact someone out of clinic hours with any important concerns or urgent questions you may have about the treatment, its side-effects or any other symptoms.

The responsibilities of joining a trial

The researchers have set up the trial to answer specific questions. Nobody gains if the trial is unable to answer those questions. So it is important that you follow the rules of the trial as far as possible, and tell your doctor if you cannot follow any of them. For example, if you find it difficult or forget to take

trial tablets, it is best to let the researchers know so that they can interpret the trial results properly.

Even though all the tests and restrictions might seem like a lot of trouble, they are designed to protect you against unknown side-effects, and to get reliable information about the treatment. Making an effort to follow the rules of the trial can benefit everyone.

It may be helpful to ask the researchers to spell out your responsibilities at the start of the trial. For example, you may find that you have to miss a clinic visit, or you might forget to take the trial drug. Check whether these may affect your rights to continue in the trial.

For safety reasons, it is worth taking some time to tell the researchers about any relevant aspects of your medical history, such as previous drug allergies or any other treatments you are currently taking. You may also be asked if you are taking any recreational drugs.

It is important to tell the researchers about any new symptoms you may experience, even such things as rashes and headaches. These may seem unimportant at the time, or you may suspect that you are on a placebo and that therefore these are not side-effects of the drug. However, you may be wrong. It is your responsibility to tell

researchers in order to give them the maximum information with which to judge the harms and benefits of the treatment.

The best protection against serious side-effects during a clinical trial is to learn about the symptoms of possible side-effects. Promptly notify the investigators whenever there is a change in your health – even if it is only a headache or rash.

Deciding not to join a trial

If you decide not to enter the trial, or if you decide to leave the trial after it begins, you still have the right to the same medical care that any other person receives.

Remember that you are not necessarily saying 'no' to all clinical trials. Make sure that you keep up-to-date about other options and new trials.

Leaving a trial

You and your doctor might decide that you stop a trial treatment if your condition is getting worse and the therapy is not helping you. Do not feel bad about leaving trials because of side-effects. This information will help others in the future.

The researchers will usually want to continue to follow your progress after the trial, even if you left it early. This helps them to interpret the results of the trial accurately.

- A clinical trial is a research study used to assess the benefits and risks of a new treatment.
- There are various methods of comparing treatments within trials. Some allocate treatment at random; some allow participants to know which treatment they are taking whilst others do not; and some allocate some participants to receive a dummy drug rather than the trial drug.
- All trials lay down criteria for who can and cannot join the trial.
- All participants must give their fully informed consent to take part in the trial. Asking questions of your doctor and researchers involved in running the trial is part of the process of giving informed consent, and we suggest some relevant questions in this booklet.
- You should not feel pressurised into joining a trial. Similarly, don't join a trial if you feel unsure you want to take part. However, you are free to leave a trial at any time, if you choose.

accrual The process of recruiting participants into a clinical trial.

CD4 A molecule on the surface of some cells onto which HIV can bind. The CD4 cell count roughly reflects the state of the immune system.

clinical trial A research study with people, usually to find out how well a new drug or treatment works in people and how safe it is.

comparison trial A trial in which experimental drugs are tested against each other or against an approved drug.

control group A group of participants in a trial who receive standard treatment rather than the experimental drug which is being tested.

dose escalation trial A study in which the amount of the drug is increased in steps until the researchers find the highest dose of the drug which can be used without causing harm.

endpoint A measurable change in the condition of a person in a clinical trial which is used to assess whether or not a therapy is working e.g. a rebound in viral load.

expanded access Programmes which make an experimental drug available to people who do not qualify for the clinical trials.

in vitro Experiments conducted in laboratories, from the Latin for "in glass".

in vivo Experiments conducted in humans or in live animals, from the Latin for "in life".

Karnofsky score A number between 0 and 100 which is assigned by a doctor to describe a patient's ability to function, as measured by the performance of common tasks. 90-100 is normal, 30 means the person is hospitalised.

pharmacokinetics The study of how a drug is absorbed and distributed in the body.

phase I The earliest stage of a drug trial in humans, designed to see if a drug is safe and what the maximum safe dose is.

phase I/II Stage of a trial to see what the most effective dose of a drug is.

phase II Stage of a trial to see if a drug is effective in the short-term.

phase III Stage of a trial when the experimental drug is given to large numbers of people, at the dose determined in phase I or II. Often the trial drug is compared with a treatment already in use or with an inactive placebo.

placebo A pill or liquid which looks and tastes exactly the same as the real drug, but contains no active substance.

undetectable viral load Viral load that is too low to be detected by the viral load test used. This usually means that you are at low risk of disease progression or of developing resistance to any drugs you are taking.

viral load nadir The lowest point to which viral load falls after you begin treatment.

Notes

Notes

Notes



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from the Department of Health

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Fifth Edition 2008

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photography Photos.com

print Lithosphere

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