

## What is a Clinical Trial?

Clinical trials are used in medical research to investigate the safety and effectiveness of some form of intervention for an illness, whether in the form of a drug, a device, or a procedure.

Generally there will be information available on the quality and general safety of the drug or device from usually small pilot studies sometimes involving healthy volunteers. The trials may also test the effectiveness of an existing intervention or drug in a new setting, or with a different dose.

In a clinical trial subjects are normally assigned at random to two or more different treatment groups. This can be to compare two different treatments, or sometimes a treatment versus no treatment or alternatively a placebo.

A placebo is something that is not an active treatment and has no clinical effect. Giving this to subjects in the trial randomised not to receive a treatment means that they are 'blinded' as to what they have received. This eliminates any bias introduced by telling someone they are receiving treatment. This can have a positive effect in itself known as the 'placebo effect'. If the medical team is also blinded to the treatment that the patient is receiving the trial is said to be 'double blind', which eliminates any potential bias on their part.

People recruited for clinical trials must give their consent for this to happen. This means they must be made fully aware of what the trial involves with all the pros, cons and any anticipated risks involved. The subject and the professional recruiting them will then sign a consent form to say that the subject is happy to enrol. However, subjects are still entitled to leave a trial at any time. Provisions will still be made for ongoing care without any disadvantage or prejudice to the volunteer. Should something unexpected occur

the subject is still entitled to complain through the normal channels or to seek compensation. All clinical trials are fully evaluated by a local ethics committee before starting by a local ethics committee. This process is now completely standardised throughout the UK. The ethics committee is a panel with some scientists, doctors and other health care professionals, but also volunteers from the general public. This ensures that clinical trials are examined from a variety of perspectives before they are given permission to proceed.

Once started, clinical trials can be run at one hospital, several hospitals, or involve centres in different countries. Charities or companies may be involved in funding clinical trials, but they are not directly involved with subjects in the trial. Overall responsibility for ensuring that a trial is being properly and ethically conducted still resides with the hospital where the trial is conducted.

Clinical trials are critical for advancing medicine and improving treatment for patients. However, enrolment is entirely voluntary and must involve people who are fully informed. The systems in place are there to ensure this is done safely and responsibly without exposing subjects to risk or harm. Almost all successful treatments used in modern medicine today have been developed because of the selfless sacrifice of patients volunteering for clinical trials.

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