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What does randomisation mean?

This information explains the role that randomisation plays in ensuring the authenticity of results from clinical trials.

Clinical trial design

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. Usually subjects are assigned at random to one or two or more different treatment groups. This can be to compare two or more different treatments, or sometimes a treatment versus no treatment. Generally a trial aims to answer a question, such as whether a treatment is helpful, and it does so by comparing an 'end point' such as symptom control or survival in people allocated to the different treatment groups.

Bias

There are numerous factors that can affect whether the question addressed by a trial is accurately and honestly answered. These factors are said to 'bias' the results. Bias in clinical trials may be described as systematic errors that encourage one outcome over others. The potential effect of bias is that investigators will come to the wrong conclusions about the beneficial and harmful effects of interventions.

The main purpose of randomisation is to avoid bias by distributing the characteristics of patients that may influence outcome randomly between treatment groups so that any difference in outcome can be explained only by treatment. These characteristics might be demographic ones such as age or prognostic factors such as clinical history or disease severity.

How do we randomise?

Randomisation can be as straightforward as rolling a dice or flipping a coin but these methods may result in uneven numbers in the groups. Opening a numbered envelope with the treatment allocated to that patient written inside is popular but near the end of the trial may allow people to guess which group is most likely to come up next, potentially introducing bias. One of the most common methods is to use a computer program to allocate patients to group at random.

Why is randomisation important in clinical trials?

Clinical trials are critical for advancing medicine and improving treatment for patients. The science of clinical trials has evolved to ensure they are properly conducted and have useful results. There is scope for researchers to influence results by the way they conduct their trial, whether inadvertently or on purpose. Trials are often very expensive and there may be the potential for pressure on researchers from their hospital, institution, funding bodies, companies or other interested parties. Essentially randomisation means that the medical team does not choose which treatment group the subject is allocated to, eliminating bias at this stage. This is one of many steps in the design of clinical trials to ensure they accurately and honestly answer the questions asked.

See also the AF Association factsheet: What is a clinical trial?

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