

Clinical Trials, Why are they necessary?

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Why are they necessary?

In recent times, patients with IBD have had a unique opportunity in Australia to be involved with cutting edge medical research and in the development of new treatments for their disease. Until as recently as last year, there were very few if any clinical trials being run in the IBD area not only in Australia but also the rest of the world. Australia has an excellent reputation worldwide for carrying out quality medical research in areas such as cancer and infectious diseases. This article aims to dispel the myths and intrigue surrounded by the words "clinical trial" and hopefully will explain how people affected with IBD can benefit by being involved.

What do we mean by clinical trials?

Before any product can actually reach the clinical trial stage it must satisfy authorities (pharmaceutical industry as well as government) that it is beneficial in its use. This means that the drug is likely to have had extensive testing in the laboratory showing that the benefits outweigh the side effects. These sets of studies are called pre clinical testing of drugs and are usually carried out in animal models of the disease. Clinical trials are really studies taken in a group of patients with a specific disease and trying to answer a specific question. For example, in trial of patients with Ulcerative Colitis the study might look at two different formulations of the same drug. The study may look at which formulation if any, is more beneficial in treating a relapse of the disease. Clinical trials are generally divided into four phases:

Phase 1 studies are carried out in a small group of patients (about 15) that DO NOT have the disease. This is to make sure that the drug does not have any nasty side effects that may otherwise be masked by the disease. Such subjects taking part in phase 1 studies are monitored very closely. They are usually admitted to special units in hospitals set up for this purpose and may have blood/urine samples and blood pressure reading at set times. If the study is successful the next stage is carried out.

Phase II studies are carried out in a group of patient with the disease. The aim of this phase is to look at the safety of the drug and side effect profile.

Phase III studies are quite similar to phase II but are carried out in a large number of patients. Once all the above data is put together, it is analysed scientifically by various committees who are specialists in the disease. The data is presented to authorities such as the Therapeutic Goods Administration (TGA) in Australia or the Food and Drug Administration (FDA) in the USA. If the drug passes all the criteria it is then made available to the public.

Phase IV studies are usually post-marketing studies looking at cost of treatment. This means that these types of studies are carried out once the drug is available to the public.

All phases of Clinical Trials are run to strict international guidelines. In Australia, we work to Good Clinical Practice Guidelines (GCP) as well as International Committee of Harmonisation (ICH) guidelines. The guidelines have been put in place to protect you as the patient and make sure that anything recorded for the trial is appropriately documented and is a true account of what happened.

This is why it takes so long to develop any new therapy. It also costs millions of dollars!!!

Taking Part in the Clinical Trials

Clinical trials are carried out all over the world from Russia to Australia and all countries should run the study the same and to the above guidelines. Before the clinical trial can commence at the institution taking part it must satisfy the institution that it is a beneficial trial run to the GCP and ICH guidelines.

Institutions such as hospitals have Ethics Committees that approve all clinical trials being run at their institution. The committees include doctors, lawyers, priests and members of the public.

When patients are invited to take part in a clinical trial they will be handed a Patient Information Sheet. This sheet describes the trial including why the trial is being run, what the side effects might be, what procedures will take place (eg. blood tests), and how long you are expected to take part in the trial. The Ethics Committee of the study center the patient will be attending has approved This Patient Information Sheet. Any patient taking part in a clinical trial, can withdraw from the trial at any point for any reason. Participation is purely voluntary. In fact before anything related to the trial can be carried out, patients must sign a Patient Informed Consent Form. This is usually attached to the Patient Information Sheet. All patients should be given a copy of the above documents to take home. They also should be informed of any new information that arises during the trial about the drug used. This whole procedure is called Informed Consent.

Access to your Medical Records

Informed Consent also involves allowing clinical trial staff to have access to personal medical records. The sole purpose of this is to make sure that what is in personal medical records matches up with what has been written in the study forms that need completing. Each patient's identity remains confidential and in fact, the forms for the trial only contain individual initials and a specific study number is assigned to each patient.

Randomisation and Placebo

In order to see the true effect of any drug treatment in a clinical trial, the study must be unbiased. This means that in a well-designed clinical trial the patient and the doctor and study personnel do not know which of the treatments being looked at that the patient is on. This procedure is called randomisation. Patients are usually randomly assigned into the different treatment groups of the trial by "chance" much like tossing a coin, and in a blinded fashion. In case of an emergency, the information is available to the doctor.

Why do we need Clinical trials?

We need clinical trials to develop new products that will benefit illnesses. New drugs and therapies provide more choices and options for patients. This means that when we know that a drug has been properly developed we can make an informed choice about whether we would like to use it. This informed choice is based on a lot of data generated on the drug by carrying out clinical trials. People taking part in a clinical trial are also obtaining access to new treatment, free of charge that is not available to everyone else. Generally patients also get the opportunity to see their doctor on a much more regular basis and are monitored very closely.

Why this trial is important to Australia?

Clinical trials in the IBD field have to date been few and far between. In recent times, Australia has been given the unique opportunity by pharmaceutical companies developing new IBD therapies to take part in such research. Taking part in clinical trials in new IBD therapies gives patients, access to the very latest in drugs to treat IBD. If these studies can be run successfully in Australia, it may mean that a lot of pharmaceutical companies will want to carry out more research here. This decision is not only good for patients but for our medical community. What this means to patients in Australia: Patients in Australia can now have access to the very latest of therapies and be involved with cutting edge research. Trial drugs are provided free of charge and people get opportunity to see their doctors and thus be closely monitored for their IBD on a very regular basis.

For more information <http://www.controlled-trials.com/> or <http://www.actr.org.au>