



Uveitis Information Group Fact sheet

What is a Clinical Trial & how to take part?

Please use this fact sheet as background information to help discussion with your doctors. Individual cases may vary enormously and so the best information will always come from your doctors. The information in this sheet has been checked for accuracy by leading Uveitis Specialists.

Clinical Trials

If you have been diagnosed with uveitis, you may want to consider participating in a clinical trial of new or improved treatments.

In order to help you in your considerations, we provide a list of current trials, the specialist in charge of it and related information including all the necessary forms. This should be enough information to allow you to discuss your participation with your family, friends and doctors.

The UIG does not advise people on whether or not a particular clinical trial is suitable for you. This should be discussed with your doctors.

This Clinical Trials section has been written in conjunction with uveitis specialists involved in clinical trials, in order to ensure maximum accuracy.

Please read the information below and follow the link at the top or bottom of page to take you to a list of current clinical trials.

What is a Clinical Trial?

A clinical trial is a type of research that tests one treatment against another. It may involve patients or people in good health, or both. It may involve newly created medications or medications that have already been in existence, but have not been used with a particular condition.

Doctors, other health professionals and patients need evidence from clinical trials to know which treatments work best with which particular condition. Without evidence, there is a risk that people could be given treatments that have little or no effect, waste resources and might be harmful.

A Clinical Trial is designed to establish:

- Whether the new treatment is safe,
- Whether the new treatment has any side effects, and
- Whether the new treatment is better than available standard treatments.

Clinical Trial Phases

Clinical trials are conducted in phases. The trials at each phase have a different purpose and help answer different questions:

In [Phase I trials](#), researchers test an experimental drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

In [Phase II trials](#), the experimental study drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

In [Phase III trials](#), the experimental study drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

Randomised Trials

In a randomised trial, half the patients are chosen at random to get the treatment being tested. They are the treatment group. The other half receive the standard treatment. They are called the control group. Doctors and researchers compare the outcomes of the treatment group to the control group. You will not be able to decide which group you enter – this is assigned randomly.

In a single-blind study, patients do not know whether they are in the treatment group or the control group.

In a double-blind study, neither the patients nor their doctors know which group they are in.

The purpose of blind studies is to make sure the results are not biased by anyone's hopes for a certain treatment.

Why participate in a Clinical Trial?

Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

Guidelines for participation in Clinical Trials

All clinical trials have guidelines about who can participate. The factors that allow someone to participate in a clinical trial are called "inclusion criteria" and those that disallow someone from participating are called "exclusion criteria". These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy

participants. The criteria help ensure that researchers will be able to answer the questions they plan to study and help to ensure that participants are appropriate for the trial and are safeguarded.

What is informed consent?

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study. Then the research team provides an [informed consent document](#) that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

What is a control or control group?

A control is the standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

What is a placebo?

In clinical trials, experimental treatments are often compared with placebos to assess the experimental treatment's effectiveness. A placebo is an inactive pill, liquid, or powder that has no treatment value. In some studies, the participants in the [control group](#) will receive a placebo instead of an active drug or experimental treatment.

Things to think about

If you decide to take part in a clinical trial, you should understand that: The treatment being tested may or may not help you. You may get better, you may see no change or you may get worse.

Your participation helps doctors learn more about the treatment being tested. This knowledge may help many patients in the future. It may not help all the patients who are in the trial.

Some trials offer experimental treatments that you cannot receive outside the trial. Other trials compare standard treatments that you may be able to receive without being in the trial.

What should you consider before participating in a trial?

You should know as much as possible about the clinical trial and feel comfortable asking your doctors and members of the clinical trial team questions about it, the care expected while in a trial, and any associated costs and potential adverse reactions. You should find out things such as:-

1. What is the purpose of the study?
2. Do I have to take part?
3. What will happen to me if I take part?
4. What do I have to do?
5. What is the drug being tested?
6. What are the alternatives for treatment?
7. What are the side effects of any treatment received while taking part?
8. What are the possible disadvantages and risks of taking part?
9. What are the possible benefits of taking part?
10. What if new information becomes available?
11. What happens when the research study stops?
12. Will my taking part in this study be kept confidential?
13. What will happen to the results of the research study?
14. Who is organising and funding the research?
15. Who has reviewed this study?
16. Who can I contact for further information?

What kind of preparation should a potential participant make for the meeting with the research coordinator or doctor?

Plan ahead and write down possible questions to ask.

Ask a friend or relative to come along for support and to hear the responses to the questions.

Bring a tape recorder to record the discussion to replay later.

Uveitis Information Group
South House
Sweening
Vidlin
Shetland Isles
ZE2 9QE
Tel 0845 604 5660
email: info@uveitis.net
website: www.uveitis.net

Revised by Uveitis Information Group (UIG) 3rd September 2009