Patient Journey in an Eye Trial

Initial Screening Visit and Discussion with the Study Doctor

Prior to your first clinical trial appointment, a Study Doctor (an ophthalmologist) and a Study Coordinator will discuss the trial and provide written information about the trial (Participant Information and Consent Form).

Your first appointment will be a screening visit where the study team will further discuss the trial and answer any questions. If you choose to proceed, both you and the Study Doctor must sign the Consent Form.

Some possible questions for considering prior to agreeing to participate in a clinical trial may be found here:

At the screening visit, you will undergo a series of procedures to ensure the clinical trial is suitable for you and your eye condition.

If you do qualify for the study, a second visit will be arranged for you to begin the study treatment. Treatments may include: injections into or around the eye, eye drops, oral medication or a medical device.
A Study Coordinator will meet with you before you start in a study, and at every study visit. Study Coordinators will speak to you about what to expect at each of your study appointments. They will also provide their contact details to allow contact with them directly at any time during the study.

All of our Study Coordinators are orthoptists (allied health professionals specialising in the eye). They will carry out many of the assessments required during the study, such as measuring your vision, measuring eye pressure, recording your medications and medical history, and performing scans and photographs of your eyes.
At each study visit, you will undergo a comprehensive vision test. The orthoptists will measure which lenses give you the best vision (refraction). You will then be asked to read the letters on the chart.

Orthoptists will also ask you about your current medications (including vitamins and over the counter medications) and your medical history. Orthoptists will also measure your blood pressure, and in some cases height, weight and temperature.
Eye Scans

We use multiple machines to obtain images of your eyes. One of the most common is the OCT, meaning Optical Coherence Tomography. An OCT test uses near infra-red light to measure the thickness of structures of the eye. It can monitor changes in the retina (the layer at the back of the eye) which can be affected in eye diseases such as macular degeneration. The test is safe and painless, taking only a few minutes to perform. OCTs are performed at most study visits.
Some studies require fluorescein angiography (often referred to as the ‘dye test’) to better assess the blood vessels in the retina at the back of the eye. A small amount of a fluorescent dye is injected into a vein in your arm, while a photographer takes photographs of the back of your eye with a special light. It takes only seconds for the dye to reach your eye. Photographs are taken for five to ten minutes. Fluorescein angiograms may only be performed once or twice a year.

There are some rare risks associated with the use of the dye and your Study Doctor will discuss these with you prior to this test.
Laboratory Tests

Most studies require blood and urine tests, both at the beginning of the study to ensure you qualify and throughout the study to monitor your overall health and response to the study medication. These are usually taken as part of your visit.

We have a dedicated laboratory on site to process these samples and then they are often sent to a central laboratory to analyse.
A Study Doctor involved in the study will examine your eyes. They will use a special microscope to give them a magnified view of the front and back of the eye.

Following this the Study Doctor will be able to determine whether the trial is suitable for you. Clinical trials often have specific criteria and not all patients will be suitable. If this is the case, the doctor will discuss this with you.

If you are found to be eligible, you will be booked for a ‘baseline’ visit where you will undergo your first study treatment. In some cases this can occur on the same day.

In many clinical trials we compare two or more treatment options, or where there is no currently approved treatment, a new treatment to a placebo (or pretend treatment). You will be assigned to a treatment group at your baseline visit. You, your Study Doctor and Coordinator cannot influence which treatment you receive and may not be aware of which treatment group you are in. This is called ‘masking’. Masking is common in clinical trials and ensures that results that are obtained during the study are not influenced by any expectations.
Many of our clinical trials involve treatment by an injection into the vitreous (jelly part inside the eye) through the sclera (white part of the eye), known as an intravitreal injection. This ensures the medication is delivered where it is needed. Injections into the eye are now a routine treatment for many eye diseases including age-related macular degeneration (AMD), diabetic macular oedema and retinal vein occlusions. Most studies involve multiple injections – the frequency and number will depend on the study and, in some cases, how your eye responds.

The treatment is performed by a Study Doctor in a dedicated treatment room, with an orthoptist or nurse assisting. If the study is ‘masked’, the doctor and assistant will be different to the staff who perform your other assessments. You are seated in a reclining chair and will receive local anaesthetic to numb the eye before the injection. The eye and surrounding skin are cleaned thoroughly with an antiseptic solution to kill any germs. Your eyelid is held open with a special instrument and the injection is placed through the white part of the eye into the jelly like substance inside the eye. The eye is then rinsed out after the injection has been completed. The whole procedure takes 10-15 minutes.

It is generally a painless procedure. Some people describe the injection as feeling like “pressure” on the eye whilst others are aware of a brief pricking sensation. Most experience dryness and grittiness in the eye for about 24 hours following the treatment, which is normal.

As with any procedure, there are some risks associated with the injections. The main risk is an eye infection. A sterile procedure is followed to minimise this rare event. Sometimes the injection causes bleeding of a small blood vessel on the white of the eye. Although this may look unpleasant for a few days, it is not a dangerous side effect. Other risks are even rarer and your doctor will explain these to you before treatment.
Your Appointment Schedule

Before you leave the clinic the Study Coordinator will book your next appointment and you may be provided with a schedule of appointments for the duration of the trial.

The amount of time you will be at the clinic will vary between studies and will depend on what is required at each visit. Most visits take between 2-3 hours. There are generally more assessments required for a clinical trial than for a standard clinic appointment, however the waiting time between assessments is usually less.

Clinical trials vary in length from several months to years. You will be informed at the start of the trial about its anticipated length.
Glossary of terms

**Baseline visit** – The visit where the first study medication is given. This is often the second visit, following the screening visit.

**Clinical Trial** - A research study in which people volunteer to test new treatments or interventions to determine their safety and effectiveness on health-related outcomes.

**Informed Consent** – A process by which a participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant’s decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

**Intravitreal** – Into the vitreous – the jelly-like substance inside the eye. The eye injections performed in most of our trials are intravitreal injections.

**Masking** - The process in clinical trials where the participant and/or study staff do not know which treatment group participants are allocated to. Masking is common in clinical trials and ensures that results that are obtained during the study are not influenced by any expectations.

**OCT** - Optical Coherence Tomography. An OCT test uses near infra-red light to measure the thickness of structures of the eye.

**Ophthalmologist** – A doctor who specialises in the eyes

**Orthoptist** – An allied health professional who specialises in the eyes

**Placebo** - A pretend treatment. A placebo appears identical to an active treatment, but does not contain any active ingredient. Placebos are used sometimes in clinical trials to enable researchers to compare treatments and retain masking

**Refraction** – The process of finding the strength of lenses that provide the best vision.

**Screening Visit** – The first visit in a clinical trial where a series of tests are undertaken to ensure the trial is suitable for the participant.