THE RETINA CARE CENTER

Clinical Trials

Frequently Asked Questions (FAQs)

Your doctor has identified you as having a retinal problem for which there may be an alternative treatment to the current standard of care. You may be eligible to participate in a new CLINICAL TRIAL. This information sheet is designed to provide you and your family with information that will help you make an informed decision about whether or not to participate.

WHAT IS A CLINICAL TRIAL?

A clinical trial is a scientific study that is designed to answer specific questions about a new drug, device, or procedure. It may be comparing a new drug to an existing drug to determine whether it is EQUIVALENT or MORE effective, or it may be investigating a new drug for a disease that has no current therapy.

There are several types or "phases" of Clinical Trials. The Retina Care Center participates in Clinical Trials of medications, devices, or procedures that have already demonstrated safety and effectiveness in smaller trials on human subjects.

WHAT ARE THE BENEFITS?

Patients may have access to a new, more effective treatment that on average may not be available to the general public for 5 years.

In many cases, all treatment costs associated with the clinical trial are paid for by the company that sponsors the trial. Expenses for treatment of the other eye may also be covered.

Patients are provided monetary compensation from the Study Sponsor for participating in a clinical trial ("Patient Stipend").

Patients will be making a contribution to the advancement of science and treatment of this particular disease. Participation could help future generations and future family members with this problem.

WHAT ARE THE NEGATIVES?

The medication being tested may NOT be more effective, or possibly worse, than current therapy.

The medication being tested may have eye or health related side effects.

AM I AUTOMATICALLY "IN" THE STUDY? WHAT IS A SCREENING VISIT?

Your doctor has identified you as a possible candidate for a clinical trial.

In order to "qualify" or to be officially accepted into the study, you must be evaluated in a "Screening Visit". This visit will determine whether your eye has the exact type and stage of disease the trial wishes to study and that certain medical or ocular conditions are not present. For example, patients with a prior history of treatment for wet Age Related Macular Degeneration (AMD) or evidence for active Diabetic Retinopathy (DR) are often ineligible for a wet AMD trial.

At a minimum, you can expect to have the following performed on a Screening Visit:

- Measurement of the vision in each eye,
- Diagnostic tests (OCT, fluorescein angiography, etc.) to determine the type and extent of disease,
- Complete Medical, Family, and Social History,
- Review of all medications,
- Blood testing

Because of the amount of information that needs to be collected during a screening visit, we advise patients that this visit may last up to 6 hours in length.

Each Clinical Trial may have slightly different inclusion criteria. The results of all of your testing will determine whether your eye is eligible for a particular Clinical Trial.

HOW OFTEN WILL I HAVE TO RETURN FOR EVALUATION AND TREATMENTS?

Each trial has their own schedule of visits but as a general rule, wet AMD studies can require patients to return to the research facility on a monthly basis between 6 months and up to 2 years, while diabetic studies can require monthly visits between 6 months and up to 3 years.

Depending on the study protocol and results of the testing performed on each individual study visit, patients may or may not receive treatment on any given study visit.

WILL I RECEIVE THE NEW MEDICINE?

In order to answer the question of whether a new medicine is better, equivalent, or worse than a current medicine, a comparison must be made. This means that some patients will receive the study medication and some will receive the treatment that is currently in use (standard of care). There is usually no less than a 50/50 chance of receiving the new medicine.

WILL I KNOW WHAT MEDICINE I AM RECEIVING?

In order to reduce bias, or the chance that the outcome of the study could be influenced by whether the patient or the doctor knows which medication the patient is receiving, multiple steps are taken to "mask" the treatment. This means that only the treating Doctor and the "unmasked" Study Coordinator are permitted to know which treatment a patient is receiving. The treatment is only revealed after the conclusion of the study or under special circumstances.

HOW IS THE MEDICINE GIVEN?

The vast majority of eyes with wet AMD are treated with medications that are carefully injected into the eye after the eye is anesthetized or "numbed". Your doctor and his team will ensure that your eye is anesthetized as much as possible before any injection is performed.

WHAT ARE THE SIDE EFFECTS?

Patients may feel some pressure during the injection but there are typically very few side effects. These may include a stinging or burning sensation, a red eye, or a gritty feeling in the eye when the numbing medicine wears off. The most serious potential side effect of injection is an infection in the eye that can happen in 1 in 5000 injections. Once recognized, this condition must promptly be treated using antibiotics, as there is a risk of permanent vision loss.

AM I PERMITTED TO WITHDRAW FROM THE STUDY?

Any patient enrolled in a Clinical Trial must understand that he or she would need to adhere to a very specific timetable of visits. We understand that circumstances may occur that could make keeping this schedule difficult. We will make every effort to assist you in adhering to your schedule of visits; however, if you find that you are unable to continue for ANY REASON, you may withdraw from the study and be treated with standard of care therapy, as would any other patient of the practice.

Similarly, if your Doctor does not feel that continuing in the study is in your best interest, he may also recommend that you withdraw from the study. To date, very few enrolled patients have withdrawn or been withdrawn from a study.

WHAT IF I DO NOT HAVE INSURANCE OR WILL MY MEDICAL INSURANCE BE BILLED?

It is not necessary to have medical insurance to participate in a Clinical Trial.

Depending on the particular Clinical Trial, your medical insurance may not be charged, including treatment of the other eye, if you're being treated for the same condition.

WILL I BE PAID?

Yes. You will be eligible for a per visit Patient Stipend ranging between $40 and $75. The exact amount will vary depending on the Clinical Trial. You may also be eligible for a Travel Stipend to cover the cost of round trip transportation from your home to the office. In some cases, you would not be eligible to receive both a Patient Stipend and a Travel Stipend.

IS THERE TRANSPORTATION ASSISTANCE AVAILABLE?

Currently, all Clinical Trials are conducted at our Baltimore, Maryland office. We recognize that this may present a significant obstacle for patients who do not have a way to travel to this office or who do not have a family member or friend to bring them.

Patients may be eligible for a Travel Stipend or Car Service. Space permitting, a friend or a family member may accompany the patient on these trips. The Study Coordinator would be happy to discuss the options available to you.

WHAT HAPPENS IF I CANNOT MAKE AN APPOINTMENT?

We recognize that emergencies and weather related events do happen and that there may be times when a patient is unable to keep a follow up visit. In this situation you will be offered an alternative make-up date on which to return.

WHAT'S NEXT?

Your next step is to decide whether you want to participate in a Clinical Trial.

You should expect a call from one of our Clinical Coordinators (Carol or Sheila) to answer any additional questions.

If you are interested in participating, she will schedule your Screening Visit and arrange for transportation, if needed.

If you are uncertain and have additional questions, she will be happy to try to answer them.

If you decide that you do not want to participate in a Clinical Trial, she will schedule you to return to the office for standard therapy.

THANK YOU FOR YOUR TIME

We at The Retina Care Center thank you for reading this information, sharing it with your family, and considering participation in one of our Clinical Trials.

It is our mission to provide the very best care to our patients with sight threatening disease. This includes offering newer treatments in development that may offer better outcomes than current standard therapy.

Please let us know if there are any other questions we can answer for you (410) 377-7611.

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