



**Intravitreal Ranibizumab
or Triamcinolone Acetonide
as Adjunctive Treatment to
Panretinal
Photocoagulation for
Proliferative Diabetic
Retinopathy**

*A multi-center study being conducted
by the Diabetic Retinopathy Clinical
Research Network*

**General Information
for Patients Considering
Becoming a Subject in This
Study**

Your eye doctor is taking part in a government study being conducted by the Diabetic Retinopathy Clinical Research Network. This network includes over 100 eye centers in the United States that specialize in the care of patients with diabetic retinopathy.

The study is being funded by the National Eye Institute, which is a part of the National Institutes of Health, a branch of the U.S. Department of Health and Human Services that funds medical research. Additional funding is being provided by Genentech, Inc., the company that makes one of the drugs being studied.

This brochure briefly describes the study and what is involved if you take part. If you think you might be interested in taking part in the study, you will be given a document called an Informed Consent Form, which will explain the study in more detail. The study center staff will answer any questions you have. You will be given as much time as you need to decide if you want to take part in the study.

You are being asked to take part in this study because your eye doctor has determined that you need laser treatment for abnormal blood vessel growth on the surface of your retina (called proliferative diabetic retinopathy). The type of laser treatment you need is called panretinal photocoagulation or PRP for short. PRP has been proven to be beneficial for proliferative diabetic retinopathy. However, in some cases it can temporarily worsen visual acuity due to swelling in the center of the retina. This swelling is called diabetic macular edema, or DME.

This study is being done to find out if this worsening of vision due to PRP can be prevented by injecting a drug into the eye.

This brochure will first tell you about diabetic retinopathy and the treatments that are part of the study. Then it will explain what is involved if you want to be part of the study.

What is Proliferative Diabetic Retinopathy?

Proliferative diabetic retinopathy means that as a result of diabetes, new blood vessels form in the retina. These blood vessels can bleed, which can cause loss of vision and even blindness. Placing laser burns throughout the retina, as is done with PRP, has been shown to be very effective in making the new blood vessels go away and in preventing blindness. However, these burns can cause DME, as described earlier, resulting in a decrease in visual acuity. Therefore, for a period of time after PRP, visual acuity may be decreased.

What treatment will I receive in the study?

All subjects in the study will receive PRP and additional laser treatment to the center of the retina.

In addition, some subjects in the study will receive an injection of a drug into the eye. There are two drugs that will be evaluated in the study. One drug is called a corticosteroid (“steroid”) drug. This drug is used to reduce swelling in many medical conditions. The steroid that is most commonly injected into the eye is triamcinolone acetonide (“triamcinolone”). The preparation being used in the study is specially made for injection into the eye and is approved by the FDA for use in other human studies.

The other drug is called ranibizumab. This drug blocks a substance called Vascular Endothelial Growth Factor (VEGF). VEGF plays a role in

the development of diabetic macular edema. Injections into the eye of ranibizumab have been approved by the FDA for treating a condition called age-related macular degeneration but not for diabetic macular edema. The drug has not been extensively studied for treatment of diabetic macular edema.

At the present time, we do not know if intravitreal triamcinolone or ranibizumab injections are beneficial in preventing vision loss after PRP treatment. It is possible that one or both of the types of injections will prevent vision loss after PRP treatment. However, we do not know whether the benefits of the injections will outweigh the risks. It is possible that because of side effects, the injections may not be as good as laser alone in treating the diabetic retinopathy.

What is involved with the injection?

Before the injection is given, the surface of the eye is cleaned to prevent infection. Then, numbing medicine is put on the eye and the injection is given. You will feel a slight pressure but it is usually not very painful because the needle used is about as thick as a single hair. After the injection, you may have a slight discomfort for a few days.

What are the possible side effects of the injection?

Possible side effects due to the injection itself include: (1) an increase in eye pressure, (2) the development of an infection or inflammation in the eye, (3) separation of the retina from the back of the eye, and (4) bleeding in the eye. These can be serious but fortunately they are very uncommon.

Possible side effects due to both study drugs include: (1) an increase in eye pressure, (2) haziness in the lens of the eye, called cataract, and (3) an allergic reaction.

There may be an increased risk of high blood pressure, heart attack, or stroke caused by ranibizumab. These side effects occur when similar drugs are given in large doses into the vein. The dose being given in the eye is much smaller so we think that side effects to the body will be very rare, but we can't be sure.

What treatment will I receive if I take part in the study?

All subjects in the study will receive laser treatment to both the center of the retina and the periphery (sides) of the retina. Additional treatment of the study eye will be determined by chance by a process similar to flipping a coin. There are three possible added treatments you could receive: (1) sham injection at the beginning of the study and at 4 weeks, (2) injection of intravitreal ranibizumab at the beginning of the study and at 4 weeks, or (3) injection of intravitreal triamcinolone at the beginning of the study and sham injection at 4 weeks. "Sham" means that a real injection is not given. You will not know whether you are receiving a "sham" injection or an injection of one of the study drugs. How the treatment is selected is described in more detail in the Informed Consent Form.

How long will the study last?

The study will last about one year. You will have follow-up visits at 1, 4, 14, 34, and 56 weeks.

What costs will be my responsibility?

Charges for the treatments and office visits that are part of your regular eye care and that would occur whether or not you are in the study will be your or your insurance company's responsibility, just as they would be if you were not in the study. This includes problems that might develop related to the treatments. If you do not have insurance or your insurance does not cover all of the procedures, the study may be able to pay for these.

Will I be reimbursed for travel expenses?

If you take part in the study, you will be provided \$25 for each required visit. This payment is being made to cover any costs you have related to the study visits (such as travel expenses, parking, babysitter, etc.) If you do not complete all of the visits or discontinue the study before it ends, you will be paid for the visits that you did complete.

What do I need to do to participate in the study?

As mentioned before you will be given an Informed Consent Form to read. This document will provide much greater detail about the study. If you would like to consider being in the study, we will first ask you to sign the form so that testing can be done to determine if you are eligible for the study. If you are eligible, we will again discuss the study and answer any questions you may have before you decide whether or not to enter the study. If you decide to be in the study, you will sign the Informed Consent Form a second time.