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Trial: Study of Association of Serum Factors With Diabetic Retinopathy

Purpose: This study will determine whether certain factors in the blood are associated with the severity of diabetic retinopathy.
Sponsor: Nation Eye Institute (NEI).
Design: Observational, natural history.
Number of Patients: 225.
Inclusion/Exclusion Criteria: Patients age ≥10 years and older with diabetes and diabetic retinopathy (DR) may be eligible for this study. Those enrolled will represent a range of DR from minimal to severe. This study may lead to a better understanding of how DR. Patients with a diagnosis of diabetes (types 1 and 2) and presence of DR will be entered into this study. Patients may have mild nonproliferative DR to proliferative DR (PDR) (previously treated or untreated), with or without clinically significant macular edema. Exclusion critera: Opacities of the ocular media, limitations of pupillary dilation or any other problems sufficient to preclude good quality stereo fundus photographs. Ocular disease which confounds assessment of diabetic retinopathy such as advanced age-related macular degeneration (AMD), central serous choroidopathy, optic atrophy, retinal vein occlusion, active uveitis, significant explained or unexplained visual field loss, or any other type of retinopathy or retinal degeneration. Chronic requirement for any ocular medication for other diseases such as glaucoma.
Status: This study is currently recruiting patients.
Information: Phone: 800-411-1222; e-mail: prpl@mail.cc.nih.gov.

Trial: Safety and Efficacy of Ranibizumab in Diabetic Macular Edema With Center Involvement (RESOLVE)

Purpose: This study will evaluate the safety and efficacy of ranibizumab (Lucentis; Genentech, San Francisco) on retinal edema and visual acuity in patients with diabetic macular edema (DME) with center involvement.
Sponsor: Novartis.
Number of patients: N/A.
Design: Phase 2, interventional, randomized, double-masked, placebo-controlled, parallel-assignment, safety/efficacy study.
Inclusion/Exclusion Criteria: DME with center involvement in at least one eye. Type 1 or type 2 diabetes diagnosed 2 years prior to screening. Laser photocoagulation in the study eye can be withheld for at least 3 months after randomization. Exclusion criteria: Patients with uncontrolled systemic or ocular diseases. Have any history of any intraocular surgery in the study eye within the past 6 months preceding screening. Conditions that require chronic concomitant therapy with systemic or topical ocular corticosteroids. Other protocol-defined inclusion/exclusion criteria may apply.
Status: This study is currently recruiting patients.
Information: Novartis customer information: +41 61 324 1111.

Trial: Intravitreal Bevacizumab vs Photocoagulation for Proliferative Diabetic Retinopathy

Purpose: The purpose of the study is to evaluate the safety and efficacy of 2.5 mg of intravitreal bevacizumab (Avastin; Genentech, San Francisco) in one eye, versus panretinal photocoagulation (PRP) in the contralateral eye, for the treatment of patients with untreated symmetric PDR. The current gold standard for the treatment of PDR is PRP. However, it is a treatment that results in significant discomfort to the patient, causes reduction of visual acuity and visual field impairment. Intravitreal bevacizumab is a novel treatment that reduces intraocular vascular endothelial growth factor (VEGF) concentration and therefore inhibits neovascular proliferation, without causing significant disconfort to the patient, nor affecting visual acuity or visual fields (although with other risks associated with intravitreal injection). Making a comparison between both treatments in different patients is difficult because there are other variables that influence the progression of the disease (such as glycemic control or renal insufficiency). Therefore this study is designed using both treatments in the same patient: intravitreal bevacizumab in one eye, compared with PRP in the contralateral eye, and evaluating visual acuity, visual fields, fluorescein angiography, optic coherence tomography (OCT) of the macula, and patient discomfort, in a 1-year follow-up.
Sponsor: Asociación para Evitar la Ceguera en México.
Design: Treatment, randomized, open-label, active control, parallel assignment, safety/efficacy study.
Number of patients: 30.
Inclusion/exclusion criteria: Symmetric PDR without high-risk characteristics, age ≥18 years and patient consent. Exclusion criteria: myocardial infarction (MI) attack or cerebrovascular attack, only eye retinal detachment, vitreous hemorrhage, previous treatment for DR, media opacities that preclude visualization of the fundus, pregnancy, inability to understands the implications of the protocol.
Status: This study is currently recruiting patients.
Information: Gerardo García-Aguirre, MD, phone: +52 55 10841400, ext. 1172; or retinamex@yahoo.com.

Trial: Laser-Ranibizumab-Triamcinolone for Proliferative Diabetic Retinopathy (LRT for PDR)

Purpose: The purpose of the study is to find out if treatment with an intravitreal injection of triamcinolone or an intravitreal injection of ranibizumab can prevent loss of vision caused by PRP treatment. At the present time, it is not known whether intravitreal steroid or anti-VEGF 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, it is not known 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 DR.
Sponsor: NEI, Genentech, and Allergan.
Design: Interventional, treatment, randomized, single-masked, active-control, parallel-assignment, efficacy.
Number of Patients: 381.
Inclusion/Exclusion Criteria: The subject must have at least one eye meeting all of the inclusion criteria and none of the exclusion criteria. A subject can have only one study eye. If both eyes are eligible at the time of randomization, the study eye will be selected by the investigator and subject before randomization. Presence of severe NPDR or PDR for which investigator intends to complete PRP within 49 days after randomization. DME present on clinical exam and central subfield thickness on OCT >250 µm, within 8 days of randomization. Best corrected Early Treatment of Diabetic Retinopathy Study (ETDRS) visual acuity letter score ≥24 (ie, 20/320 or better), within 8 days of randomization. Media clarity, pupillary dilation, and subject cooperation sufficient to administer PRP and obtain adequate fundus photographs and OCT. If prior macular photocoagulation has been performed, the investigator believes that the study eye may possibly benefit from additional focal photocoagulation. Age ≥18 years, diagnosis of diabetes (type 1 or type 2), fellow eye (if not a study eye) meets criteria, able and willing to provide informed consent. General exclusion criteria: A patient is not eligible if any of the following exclusion criteria are present: Significant renal disease, defined as a history of chronic renal failure requiring dialysis or kidney transplant. A condition that, in the opinion of the investigator, would preclude participation in the study (eg., unstable medical status including blood pressure, cardiovascular disease, and glycemic control). Participation in an investigational trial within 30 days of randomization that involved treatment with any drug that has not received regulatory approval at the time of study entry. Known allergy to any component of the study drugs. Blood pressure >180/110 mm Hg. Major surgery within 28 days prior to randomization or major surgery planned during the next 6 months. MI, other cardiac event requiring hospitalization, stroke, transient ischemic attack, or treatment for acute congestive heart failure within 4 months prior to randomization. Systemic anti-VEGF or pro-VEGF treatment within 4 months prior to randomization.
Status:This study is currently recruiting patients.
Information: Roy W. Beck, MD, PhD, phone: 866-372-7601; or e-mail: rbeck@jaeb.org; Adam R. Glassman, MS, phone: 866-372-7601; or e-mail: aglassman@jaeb.org.

Trial: Evaluation of Ranibizumab in Proliferative Diabetic Retinopathy (PDR) Requiring Vitrectomy

Purpose: Evaluation of ranibizumab on the ease and procedure and complication in PDR requiring vitrectomy. This is an open-label, phase 1/2 study of multiple doses of intravitreally administered ranibizumab in patients with severe NPDR and PDR prior to, during, and after vitrectomy therapy.
Sponsor: Retina Associates in Kansas City and Genentech.
Design: Treatment, randomized, single-masked, active control, single group assignment, safety/efficacy.
Number of Patients: 40.
Inclusion/Exclusion Criteria: Ability to provide written informed consent and comply with study assessments for the full duration of the study. Age >20 years. BCVA of 20/40 to 20/800 in the study eye. Very severe NPDR (ETDRS level 53E) or moderate PDR (ETDRS level 65). Visual reduction attributable to diabetic vitreous hemorrhage or DME Candidate for vitrectomy procedure. Exclusion criteria: Pregnancy (positive Pregnancy test) or lactation. Premenopausal women not using adequate contraception. The following are considered effective means of contraception: surgical sterilization or use of oral contraceptives, barrier contraception with either a condom or diaphragm in conjunction with spermicidal gel, an IUD, or contraceptive hormone implant or patch. Any other condition that the investigator believes would pose a significant hazard to the subject if the investigational therapy were initiated. Participation in another simultaneous medical investigation or trial. Visual impairment attributable to causes other than DME or diabetic vitreous hemorrhage. Use of intraocular or periocular corticosteroids within 6 months. History of PRP. History of macular laser photocoagulation. History of pars plana vitrectomy. Prior or concomitant treatment with ranibizumab, bevacizumab, or pegaptanib sodium (Macugen; OSI Eyetech/Pfizer, New York, NY), either as part of an investigational study or as an off-label medication. Current treatment of a systemic infection.
Status: This trial is currently recruiting patients.

Information: Lexie Manning, phone: 913-831-7400; or e-mail: lmanning@kcretina.com.

Trial: Effect of Macugen(Pegaptanib)on Surgical Outcomes and VEGF Levels in Diabetic Patients With PDR (Diabetic Retinopathy or CSDME (Macular Edema) (PEGAP001)

Purpose: Patients with PDR or clinically significant DME requiring surgical intervention will receive a preoperative injection of pegaptanib. An initial, preinjection vitreous tap will be done in order to provide baseline $VEGF_{165}$ and cytokine levels. At the onset of the vitrectomy, a second vitreous sample will be taken to obtain intraoperative levels of pegaptanib, $VEGF_{165}$ and cytokines. The goal of this study is to quantify the reduction of intravitreal $VEGF_{165}$ levels in patients following intravitreal pegaptanib injection preoperatively and determine the level of pegaptanib in the vitreous cavity after variable time intervals (2,4, 6 or 8 weeks).
Design: Diagnostic, nonrandomized, open-label, uncontrolled, single-group assignment, pharmacokinetics.
Number of Patients: 32
Incluson/Exclusion Criteria: Eighteen years or older. Type 1 or 2 diabetes. Patients requiring surgical intervention for complications of proliferative diabetic retinopathy with vitreous hemorrhage or traction retinal detachment or clinically significant macular edema. Women postmenopausal for 12 months before the study, surgically sterile, or not pregnant and on effective contraception. Exclusion criteria: Previous retinal vein occlusion, any intraocular surgery within the previous 12 months, myopia of ≥8 D, active ocular or periocular infection, treatment with an investigational agent for any condition 60 days prior to enrollment, evidence of severe cardiac disease, clinically significant peripheral vascular disease (previous surgery, amputation, or symptoms of claudication), uncontrolled hypertension (treated systolic blood pressure >155 mm Hg or diastolic blood pressure >95 mm Hg, stroke within the preceding 12 months.
Status: This study is currently recruiting patients.
Information: Thomas G. Sheidow, MD, phone: 519-685-8133; or e-mail: tom.sheidow@lhsc.on.ca

Trial: Pegaptanib Sodium (Macugen) Compared to Sham Injection in Patients With DME Involving the Center of the Macula

Purpose: The purpose of the study to determine if pegaptanib sodium is safe and effective in slowing down the leakage of fluid within the eye and thereby stabilizing or improving vision when compared to placebo injections.
Sponsors: Eyetech Pharmaceuticals and Pfizer
Design: Phase 2/3, interventional, randomized, double-masked, parallel-assignment, safety, efficacy.
Number of patients: 900
Inclusion/exclusion citeria: DME with corresponding leakage on fluorescein angiogram. Foveal thickness of at least 300 microns on OCT. BCVA in the study eye between 20/50 and 20/200. Women of childbearing potential must use two effective forms of contraception throughout the duration of the study Exclusion criteria: Prior or current need for PRP. Prior treatment with an investigational agent for DME.
Status: This study is currently recruiting patients.
Information. Call 866-622-8436 .

Trial: Screening for Studies on Retinovascular Diseases

Purpose: This screening protocol is designed to help recruit patients for NEI studies of the retina, such as DR and AMD. Patients must meet the specific criteria of a research study, and this protocol serves as a first step for admitting patients to a retinal disease study. Candidates will undergo a medical history and comprehensive eye examination. The eye examination includes dilation of the pupils to fully examine the retina. In some studies, photographs of the eye are required. This is done using fluorescein angiography. In this procedure, a dye called sodium fluorescein is injected into the blood stream through a vein. After the dye reaches the blood vessels of the eye, photographs are taken of the retina. Other diagnostic procedures may include physical examination, questionnaires, routine laboratory tests and other standard or specialized tests, as needed. When the screening is completed, patients will be informed of their options to participate in a study. Patients who are ineligible for a current study will be informed of alternative treatments or options. No treatment is offered under this protocol.
Design: Observatonal, natural history.
Patients: 2,000
Inclusion/Exclusion Criteria: Inclusion and exclusion criteria vary with the particular protocol for which a patient is being screened. In addition to those diagnoses currently under study, subjects with unknown conditions that require the establishment of a diagnosis may be eligible for inclusion in this study. All studies of retinovascular diseases require the subject to have minimum age of 18 years in both men and women.
Status: This study is currently recruiting patients.
Information: Patient Recruitment and Public Liaison Office phone: 800-411-1222; or e-mail: prpl@mail.cc.nih.gov. ■