Listings from www.clinicaltrials.gov

Trial: Genetic Study of Age-Related Macular Degeneration (AMD)

Purpose: This pilot study is will test the feasibility of evaluating the patterns of expression of genes that may be involved in the pathogenesis of AMD. The genes of interest are involved in the process of wound repair, cell injury and cell death. The investigators hope to access the expression of these genes, but in tissues taken from nonocular sites, in patients with AMD and in patients without AMD.
Sponsor: National Eye Institute (NEI)
Design: Natural history
Number of Patients: 150
Inclusion/Exclusion Criteria: Inclusion criteria 1 through 3 apply to the first 12 participants, criteria 4 through 6 apply to the last 50.
1.AMD Patients: Diagnosis of AMD defined by the presence of at least one drusen >125 µm in diameter (4 patients) or geographic atrophy (GA) in at least one eye or choroidal neovascularization with drusen of any size in at least one eye (four patients). (AMD cases only)
2. Age ≥60.
3. Age-matched control patients, absence of drusen or no more than 5 drusen <63 µm, absence of other diagnostic criteria for AMD, and age ≥60 years. The distribution of ages in the control group will be as similar as possible to the distribution of ages in the disease groups (4 patients).
4. AMD Patients: Diagnosis of AMD defined by the presence of at least one druse >125 µm in diameter (10 patients), GA (10 patients) and choroidal neovascularization (CNV) with drusen of any size in at least one eye and/or disciform scar (20 patients). (AMD cases only) Presence of neovascularization and disciform scar formation will be verified by color photography.
5 Age ≥50 years.
6. Age-matched control patients: absence of drusen or no more than 5 drusen <63 µm, absence of other diagnostic criteria for AMD, and age ≥50 years. The distribution of ages in the control group.
Exclusion Criteria: Patient aged <50 years.
Presence of retinal disease involving the photoreceptors and/or outer retinal layers other than AMD loss such as high myopia, retinal dystrophies, central serous retinopathy, vein occlusion, diabetic retinopathy and uveitis or similar outer retinal diseases which have been present prior to the age of 50 years. Opacities of the ocular media, limitations of pupillary dilation or other problems sufficient to preclude adequate stereo fundus photography. Medical problems which make consistent follow-up over the treatment period unlikely (eg, stroke, severe myocardial infarction, terminal carcinoma). Inability or inaccessibility to obtain dermal biopsy from the inner aspect of both arms due to previous trauma, underlying skin disorder which would preclude good wound healing, previous surgery of the arm or breast which could prevent good wound healing or induce other changes at the biopsy site.
Status: This study is currently recruiting patients.
Information: Please refer to this study by ClinicalTrials.gov identifier NCT00357578. Patient Recruitment and Public Liaison Office call 800-411-1222; or e-mail: prpl@mail.cc.nih.gov.

Trial: OT-551 Antioxidant Eye Drops to Treat Geographic Atrophy in Age-Related Macular Degeneration

Purpose: Othera Pharmaceuticals' Othera (OT)-551 antioxidant eye drop has the potential for chronic treatment of the dry form of AMD. This pilot study of up to 10 eye drop tolerant participants with bilateral geographic atrophy is designed to characterize the effect of 0.45% concentration of OT-551 eye drops given three times a day on the progression of geographic atrophy area over a two-year period. Participants will have one eye randomized to receive the eye drop and the fellow eye will be observed only.
Sponsor: NEI
Design: Interventional, treatment
Number of Patients: 10
Inclusion/Exclusion Criteria: Participant must understand and sign the protocol's informed consent (if the participant's vision is impaired to the point where it is not possible to read the informed consent document, the informed consent document will be read in its entirety to the participant). Participant must be able to administer the eye drops or have a caretaker administer the eye drops. Participants must have GA present in both eyes compatible with AMD. Even if much of the RPE appears to be preserved and large choroidal vessels are not visible, a roundish patch of RPE partial depigmentation may still be classified as early GA. A patch must be of size at least 1/2 disc area (DA) and less than 4 DA. Participant must have a steady fixation in the study eye in the foveal or parafoveal area and media clear enough for good quality photographs.
Exclusion Criteria: Participant is <50 years of age. Participant is in another investigational study. Participant is medically unable to comply with study procedures or follow-up visits. Participant has evidence of ocular disease other than AMD that may confound the outcome of the study (eg, diabetic retinopathy, uveitis, etc.). Participant has chronic requirement for ocular medications for diseases, that in the judgment of the examining physician, are vision threatening or may affect the primary outcome (artificial tears are

permitted). Participant has evidence of pseudovitelliform macular degeneration in either eye. Participant with evidence of vitreoretinal traction maculopathy in either eye. Participant has a history of laser, photodynamic therapy (PDT), intravitreal injection of any agent (anti-VEGF, triamcinolone, etc.), or any previous treatment for AMD other than Age-Related Eye Disease Study (AREDS) or equivalent supplement formulation in a study eye. Participant has had a vitrectomy, penetrating keratoplasty, trabeculectomy or trabeculoplasty. Participant has undergone lens removal in the last 3 months. Participant is on chemotherapy. Participant is on ocular or systemic medications known to be toxic to the lens, retina, or optic nerve. Participant has a known hypersensitivity to BAC or other components of the study drug. Participant with history of malignancy that would compromise the 2 year study survival. Participant with a history of ocular Herpes simplex virus.
Status: This study is currently recruiting patients.
Information: Please refer to this study by ClinicalTrials.gov identifier NCT00306488. Patient Recruitment and Public Liaison Office call 800-411-1222; or e-mail: prpl@mail.cc.nih.gov.

Trial: Age-Related Eye Disease Study II (AREDS II)

Purpose: AREDS2 is an NEI-sponsored study of nutrient-based factors that may influence the development and progression of the two most prevalent age-related eye diseases: AMD and cataract. Human and animal studies provide a reasonable basis for speculating that certain nutrients accreted to and concentrated in the eye have the capacity to modulate factors and processes implicated in the pathogenesis of AMD and cataract. Results from AREDS on the relationship of lutein/zeaxanthin and omega-3 long-chain polyunsaturated fatty acid (LCPUFA) intake with advanced AMD are informative, yet the non-experimental sampling (observational) design limits our strength of inference. AREDS2 is a multi-center phase 3 randomized clinical trial designed to assess the effects of oral supplementation of high doses of macular xanthophylls (lutein and zeaxanthin) and/or omega-3 LCPUFAs as a treatment for AMD, cataract and moderate vision loss. In addition to this objective, the study will provide information on the clinical course, prognosis, and risk factors for development and progression of both AMD and cataract. Other study goals include the evaluation of eliminating beta-carotene and/or reducing zinc in the original AREDS formulation on the progression and development of AMD. AREDS2 will also seek to validate the fundus photographic AMD scale developed from AREDS.
Sponsor: NEI
Design: AREDS2 is a multicenter phase 3 randomized clinical trial.
Number of patients: 52
Inclusion/exclusion criteria: Men and women aged 50 to 85 years at the Qualification Visit. Bilateral large drusen (≥125 µm) or large drusen in one eye and advanced AMD in the fellow eye. A study eye (eye without advanced AMD) may have definite GA not involving the center of the macula without evidence of drusen. Study eye(s) with fundus photographs assessed by the Reading Center to be of adequate photo quality. Pupillary dilation ≥5 mm in each eye for all participants, except that dilation less than 5 mm in an aphakic or pseudophakic eye will not exclude a participant with adequate quality fundus photographs. Randomization within 3 months following the Qualification Visit. Willingness to stop taking any supplements containing lutein, zeaxanthin, omega-3 LCPUFAs (specifically DHA and EPA), vitamin C, vitamin E, beta-carotene, zinc or copper, other than those supplied by AREDS2.
Exclusion Criteria: Ocular disease in either eye, other than AMD, which may confound assessment of the retina, including: diabetic retinopathy unless retinopathy is limited to <10 microaneurysms and/or small retinal hemorrhages, angioid streaks, central serous choroidopathy, surface wrinkling retinopathy (epiretinal membrane) that is more severe than the mild surface wrinkling retinopathy, optic atrophy, pigmentary abnormalities considered by the Clinical Center ophthalmologist to be less typical of AMD than of some other condition, such as pattern dystrophy or chronic central serous retinopathy. Myopic crescent of the optic disc the width of which is ≥50% of the longest diameter of the disc, or pigmentary abnormalities in the posterior pole considered by the clinic ophthalmologist more likely to be due to myopia than to AMD. Macular hole or pseudohole. Retinal vein occlusion, active uveitis, presumed ocular histoplasmosis syndrome, other sight-threatening retinopathies, and other retinal degenerations, significant explained or unexplained visual field loss, or any other type of retinopathy or retinal degeneration. A choroidal nevus within 2 DD of the center of the macula associated with depigmentation or overlying atypical drusen. Other ocular diseases or conditions, the presence of which may now or in the future complicate evaluation of AMD. See clinicaltrials.gov for more.
Status: This study is currently recruiting patients.
Information: Please refer to this study by ClinicalTrials.gov identifier NCT00409513. Patient Recruitment and Public Liaison Office call 800-411-1222; or e-mail: prpl@mail.cc.nih.gov.

Trial: Clinical Study Of EYE001 For Wet-Type AMD

Purpose: This study will examine the efficacy and safety of pegaptanib sodium (Macugen; OSI/Eyetech and Pfizer, New york, NY) in Japanese patients with neovascular AMD, in order to establish that there is no large difference in the efficacy and the safety of the drug between Western and Japanese patients.
Sponsor: Pfizer
Design: Phase 2, randomized, double-masked, dose-comparison, parallel-assignment, safety/efficacy study.
Number of Patients: 90
Inclusion/Exclusion Criteria: Neovascular AMD, visual acuity from 20/320 to 20/40. Exclusion criteria are diabetic retinopathy, laser coagulation history.
Status: This study is currently recruiting patients.
Information: Call 800-718-1021.

Trial: A Safety and Feasibility Study of the TheraSight Ocular Brachytherapy System for Treatment of Age-Related Macular Degeneration

Purpose: The study will investigate the safety and feasibility of using the TheraSight Brachytherapy System (Theragenics, Buford, GA) for treatment of neovascular AMD.
Sponsor: Theragenics
Design: Treatment, randomized, open-label, dose-comparison, single-group assignment, safety study, phase 1 and 2
Number of Patients: 30
Inclusion/Exclusion Criteria: Age ≥50 years, active primary or recurrent subfoveal CNV secondary to AMD with minimally classic or occult lesion. Exclusion criteria: prior AMD therapy, including but not limited to laser and PDT. (See www.clinicaltrials.gov for comprehensive listing.)
Status: This study is currently recruiting patients.
Information: Call 877-960-1234

Trial: Study of Vatalanib and Photodynamic Therapy With Verteporfin in Patients With Subfoveal CNV Secondary to AMD (ADVANCE)

Purpose: This study will test the safety of vatalanib in combination with verteporfin (Visudyne; Novartis, Hanover, NJ) in patients with CNV forming beneath the macula due to AMD
Sponsor: Novartis
Design: Phase 1 and 2, randomized, double-masked, active control, parallel-assignment, safety study.
Number of Patients: 60
Inclusion/Exclusion Criteria: Neovascular AMD, size of the lesion (if predominantly classic type) must be ≤5400 µm. If minimally classic type or occult only type, lesion must be ≤6 disc areas and must have recent disease progression. Have sight of approximately 20/40 to 20/320 Snellen.
Exclusion Criteria: Prior treatment in the study eye for this disease, uncontrolled high blood pressure, espite chronic stable treatment. History of ECG abnormalities.
Status: This study is currently recruiting patients.
Information: Contact Novartis.

Trial: Efficacy and Safety of Ranibizumab (Lucentis; Genentech, San Francisco) in Patients With Subfoveal CNV Secondary to AMD (EXCITE)

Purpose: The study will test if efficacy and safety of an alternative dosing regimen is as effective as monthly injections.
Sponsor: Novartis
Design: Treatment, randomized, double-masked, placebo-controlled, parallel-assignment, safety/efficacy study, phase 3
Number of Patients: 350
Inclusion/Exclusion Criteria: Patients with primary or recurrent subfoveal CNV secondary to AMD, including those with predominantly classic, minimally classic or occult lesions with no classic component. Patients who have a BCVA score between 73 and 24 letters, inclusively, in the study eye using ETDRS-like grading charts (approximately 20/40 to 20/320).
Exclusion Criteria: Prior treatment in the study eye with verteporfin, external-beam radiation therapy, subfoveal focal laser photocoagulation, vitrectomy, or transpupillary thermotherapy. History of submacular surgery or other surgical intervention for AMD in the study eye, glaucoma filtration surgery, corneal transplant surgery. Laser photocoagulation (juxtafoveal or extrafoveal) in the study eye within one month preceding baseline. Other protocol-defined inclusion/exclusion criteria may apply.
Status: This study is currently recruiting patients.
Information: Novartis Recruiting: +41 61 324 1111

Trial: Genetic Factors in Age-Related Macular Degeneration

Purpose: This study will examine whether certain polymorphisms predispose people to develop AMD.
Sponsor: NEI
Design: Observational/screening
Number of Patients: 400
Inclusion/Exclusion Criteria: Samples from volunteers meeting the following eligibility criteria will be included in the study. Diagnosis of advanced AMD defined by GAand/or CNV with drusen of any size in at least one eye. (AMD cases only). Age ≥50 years. If sample previously donated in a different study, the patient has given their permission to use their sample (ie, marked

appropriate selection in the informed consent).
Control Patients (controls): Age ≥70 years. Absence of drusen or no more than five drusen <63 µm, absence of other of diagnostic criteria for AMD. Agrees to undergo study examinations.
Exclusion Criteria: Samples from volunteers meeting any of the following exclusion criteria will not be included. Presence of retinal disease involving the photoreceptors and/or outer retinal layers other than AMD loss such as high myopia, retinal dystrophies, central serous retinopathy, vein occlusion, diabetic retinopathy and uveitis or similar outer retinal diseases that have been present prior to the age of 50 years. Opacities of the ocular media, limitations of papillary dilation or other problems sufficient to preclude adequate stereo fundus photography. These conditions include occluded pupils due to synechiae, cataracts, vitreous haze and opacities due to ocular diseases.
Status: This study is currently recruiting patients.
Information: NEI Patient Recruitment and Public Liaison Office, 800-411-1222; e-mail: prpl@mail.cc.nih.gov.

Trial: Double-Masked Study of Photrex (Rostaporfin) Photodynamic Therapy in the Treatment of Age-Related Macular Degeneration

Purpose: The purpose of this study is to confirm the efficacy and safety of rostaporfin (Photrex; Miravant, Santa Barbara, CA) PDT in the treatment of classic and occult subfoveal CNV associated with AMD.
Sponsor: Miravant Pharmaceuticals
Design: Phase 3, randomized, double-masked, placebo-controlled, single-group assignment, efficacy study.
Number of patients: 660
Inclusion/exclusion criteria: Patients aged ≥50 years with at least one subfoveal CNV membrane secondary to AMD that can be demonstrated by fluorescein angiography.
Status: This study is currently recruiting patients.
Information: Miravant Pharmaceuticals, 800-685-2959 or e-mail: ctinfo@miravant.com.

Trial: Age-Related Macular Degeneration: Detection of Onset of New Choroidal Neovascularization (AMD DOC Study)

Purpose: The purpose of this study is to compare the ability of the preferential hyperacuity perimeter (PH), to that of the Amsler grid in detecting neovascular AMD in eyes at high risk for CNV development. Participants will be followed-up for a period of two years, or until CNV develops in the study eye for which treatment is recommended, to determine the occurrence of CNV.
Design: Randomized, multicenter clinical study at six participating clinical centers. The fundamental design principles of thesStudy are simplicity and parsimony.
Number of Patients: 180
Inclusion/Exclusion Criteria: Age ≥50 years, BCVA letter score = ≥65 or greater (approximate Snellen equivalent of 20/50 or better in the candidate study eye). Neovascular AMD in the fellow eye and no CNV in the candidate study eye (absence of CNV confirmed by FA which will be graded in a masked fashion by the AMD DOC Study Reading Center). Candidate study eye must have evidence of at least one large druse (≥125µm) and focal hyperpigmentation within 3600 µm of the fovea and visible on color fundus photography. Participant must have media clear enough in the candidate study eye to permit fundus photography, fluorescein angiography, and OCT and absence of any fluorescein allergies. Negative PHP at baseline for the candidate study eye (potentially eligible participants who have a positive PHP for that eye at the initial screening visit will be allowed a second PHP screening visit within 2 weeks in order to repeat the PHP test; if the 2nd PHP test is positive, the participant is ineligible for follow-up in the AMD DOC study). Negative OCT findings for CNV at baseline for the candidate study eye (i.e., no subretinal fluid, intraretinal edema, or retinal thickening that falls within the top 1% of the normative data base for the Stratus OCT) confirmed by the AMD DOC Study Reading Center. See Web site for more details.
Exclusion Criteria: Known allergy to fluorescein angiography or allergic reaction during screening Advanced AMD with CNV in both eyes confirmed on FA graded by the AMD DOC Study Reading Center. Foveal geographic atrophy in the study eye.
Positive baseline PHP test or supervised Amsler grid for the candidate study eye performed on 2 successive screening visits spaced no more than 2 weeks apart. Positive OCT test for the candidate study eye, as read by the AMD DOC Study Reading Center, for subretinal fluid, intraretinal edema, or retinal thickening that falls within the top 1% of the normative data base for the Stratus OCT. Significant media opacity that precludes reasonable quality retinal imaging including color fundus photographs, fluorescein angiography, or OCT in the candidate study eye to assess the presence of CNV. Evidence of macular disease (e.g., pattern dystrophy, diabetic macular edema, vitreomacular traction) other than AMD in the study eye. Previous surgical or laser treatment to the macula of the study eye. Diabetic retinopathy.
Status: This study is currently recruiting patients.
Information: Please refer to this study by

ClinicalTrials.gov identifier NCT00417846
Susan B. Bressler, MD, 410-955-3648; or sbressler@jhmi.edu or Patricia L. Hawse, MS, 410-446-2569; or phawse@jhmi.edu.

Trial: Lucentis Utilizing Visudyne (LUV Trial) Combination Therapy in the Treatment of Age-Related Macular Degeneration

Purpose: The PDT/Lucentis trial will be a phase 4 comparative trial comparing the use of combination therapy with intravitreal ranibizumab and verteporfin PDT to intravitreal ranibizumab alone in patients with exudative AMD. Patients will be randomized to one of three groups. All patients will receive three consecutive monthly treatments with intravitreal ranibizumab. Patients randomized to group I will receive only intravitreal ranibizumab. Patients randomized to group 2 will also receive one treatment with reduced fluence (20% fluence) verteporfin PDT at day 0. Patients randomized to group III will also receive one treatment with reduced fluence (40% fluence) vPDT. All patients will also be evaluated for possible retreatment with ranibizumab according to established criteria. Thirty patients (ten per group) will be recruited from one US site in a 6-month period. Randomization will occur at the time of entry into the study. Follow-up will continue until month 12 (from day 0) in all subjects.
Sponsors: Greater Houston Retina Research and Novartis.
Design: Interventional, treatment, randomized, open label, dose-comparison, parallel-assignment, efficacy study.
Number of Patients: 30
Inclusion Criteria: Ability to provide written informed consent and comply with study assessments for the full duration of the study. Age >55 years. Subfoveal neovascular membrane confirmed by fluorescein angiography and or ICG. Visual acuity not better than 20/32 and not worse than 20/320 by ETDRS refraction
Exclusion Criteria: Any previous vitrectomy in study eye (posterior or anterior associated with vitreous loss in cataract surgery). Intracapsular cataract extraction (posterior capsule needs to be present). Previous treatment with ranibizumab. Previous treatment with pegaptanib, Previous treatment with intravitreal triamcinolone. Any previous treatment with PDT. Previous history of retinal detachment in study eye. Any previous radiation treatments to head/ neck. Significant cardiovascular disease or cancer that would prevent follow-up visits or completion of the 12 month study. Prior enrollment in any study for AMD in the study eye. Participation in another simultaneous medical investigator or trial. Ocular disorders in the study eye that may confound interpretation of study results, including retinal detachment or macular hole. Concurrent disease in the study eye that could compromise visual acuity or require medical or surgical intervention during the study period. Aphakia or absence of the posterior capsule in the study eye. Previous violation of the posterior capsule is also excluded unless it occurred as a result of YAG laser posterior capsulotomy in association with prior, posterior chamber intraocular lens implantation. See Web site for additional criteria
Status: This study is currently recruiting patients.
Information: Please refer to this study by ClinicalTrials.gov identifier NCT00423189. David M Brown, MD; 713-524-3434 or Neil T Schmitz, BA; 713-524-3434; or neil.schmitz@houstonretina.com

Trial: SUSTAIN – Study of Ranibizumab in Patients With Subfoveal Choroidal Neovascularization Secondary to Age-Related Macular Degeneration

Purpose: Ranibizumab is a humanized recombinant monoclonal antibody fragment targeted against human VEGF-A. This study will assess the safety and efficacy of ranibizumab administered on an as-needed dosing regimen in patients with subfoveal CNV secondary to AMD
Sponsors: Novartis
Design: Interventional, treatment, nonrandomized, open-label, uncontrolled, expanded-access assignment, safety/efficacy study.
Number of Patients: 500
Inclusion/Exclusion Criteria: Male or female patients >50 years of age. Diagnosis of active primary or recurrent CNV secondary to AMD, including those with predominantly classic, minimally classic or occult lesions with no classic component. The total area of CNV (including both classic and occult components) encompassed within the lesion must be ≥50% of the total lesion area. The total lesion area must be ≤12 disc areas. Patients who have a BCVA (Best corrected visual acuity) score between 73 and 24 letters, inclusive, in the study eye using ETDRS-like (Early Treatment of Diabetic Retinopathy Study) grading charts (approximately 20/40 to 20/320)
Exclusion Criteria: Patients who have a BCVA of < 34 letters in both eyes (legally blind is defined as bilateral vision below 20/200 or <34 letters). Laser photocoagulation, treatment with intravitreal steroids, verteporfin photo dynamic therapy or pegaptanib sodium in the study eye within 30 days preceding Day 1. Previous participation in a clinical trial (for either eye) involving anti-angiogenic drugs (pegaptanib, ranibizumab, anecortave acetate, protein kinase C inhibitors, etc.).

Other protocol-defined inclusion/exclusion criteria may apply.
Information: Please refer to this study by ClinicalTrials.gov identifier NCT00331864. Novartis Customer Information: 862-778-8300.

Trial: Safety and Tolerability of Intravitreal Administration of Vascular Endothelial Growth Factor (VEGF) Trap in Patients With Neovascular Age-Related Macular Degeneration (AMD)

Purpose: The purpose of this trial is to assess the ocular and systemic safety and tolerability of a single intravitreal injection of VEGF Trap (Regeneron, Tarrytown, NY) in patients with subfoveal choroidal neovascularization (CNV) due to AMD.
Sponsors: Regeneron Pharmaceuticals
Design: Interventional, treatment, safety study.
Number of Patients: 96
Inclusion/Exclusion Criteria: Subfoveal CNV secondary to AMD. Central retinal/lesion thickness ≥250 µm as measured by OCT. ETDRS BVCA 20/40 (73 letters) or worse. Clear ocular media and clear lens(es) to permit good quality stereoscopic fundus photography.
Exclusion Criteria: Prior treatment with VEGF Trap, bevacizumab or ranibizumab. Any investigational agent within 12 weeks of Visit 2 (Day 1). Presence of other causes of CNV. Active ocular infection.
Status: This study is currently recruiting patients.
Information: Please refer to this study by ClinicalTrials.gov identifier NCT00320775. Regeneron: VEGF.Trap@regeneron.com

Trial: Triple Therapy—PDT Plus IVD and Intravitreal Ranibizumab Versus Monotherapy—Intravitreal Ranibizumab Alone for the Treatment of Age-Related Macular Degeneration.

Purpose: The purpose of this study is to compare triple therapy using PDT therapy, intravitreal dexamethasone and intravitreal ranibizumab injections versus monotherapy with intravitreal ranibiumab alone for the treatment of AMD.
Sponsors: Bay Area Retina Associates and QLT Inc.
Design: Interventional, treatment, randomized, single masked, active-control, crossover-assignment, efficacy study.
Number of Patients: 60
Inclusion/Exclusion Criteria: BCVA using ETDRS Charts between 20/40 and 20/320 (Snellen Equivalent) in the study eye with evidence of neovascular AMD. (Only one eye will be eligible for study. If both eyes are eligible, the one with the better visual acuity will be selected for treatment unless, based on medical reasons, the investigator deems the other eye to be more appropriate for treatment and study.) All lesion subtypes will be enrolled with the following criteria. Predominantly classic: Classic lesion >50% of the total lesion area, lesion must be <12 disc areas, minimally classic or occult, CNVM must be ≥50% of the total lesion size. There must be some evidence of recent disease progression (heme, vision loss, recent lesion growth on FA). Lesion size must be <12 disc areas. Occult: Lesions must show recent activity progression with respect to vision, subretinal hemorrhage or subretinal fluid; <12 disc areas in total size. Signed informed consent, age ≥50 years
Exclusion Criteria: Pigment epithelial detachment greater than 50% of the total lesion size , previous treatment for AMD in the study eye, previous intravitreal drug delivery in the study eye, history of vitrectomy in the study eye, fibrosis or atrophy involving the center of the fovea in the study eye, neovascular membrane from any other concurrent retinal disease such as high myopia (SER >-8D), histoplasmosis or other ocular inflammatory disease. Known history of glaucoma and on more than one topical medication. History of glaucoma filtering surgery in the study eye. See Web site for additional criteria.
Status: This study is currently recruiting patients.
Information: Please refer to this study by ClinicalTrials.gov identifier NCT00390208. Sumie T Takahara; 925-943-6800 or stakahara@bayarearetina.com; and Cindy Moreci; 925-943-6800; orcmoreci@bayarearetina.com.

Trial: Triamcinolone Acetonide as an Adjunctive to VPDT in ARMD

Purpose: A 24- month study looking at the the changes in visual acuity of patients receiving PDT therapy in conjunction with intravitreal triamcinolone.
Sponsors: Canadian Retinal Trials Group, University of British Columbia, QLT Inc and Vancouver Hospital
Design: Phase 2,3, randomized, double-masked, placebo-controlled, parallel-assignment, safety/efficacy study.
Number of Patients: 120, expected completion December 2007.
Inclusion/Exclusion Criteria: Individuals with predominantly classic, subfoveal CNV secondary to AMD. No previous PDT treatment in study eye. Exclusion criteria: CNV from conditions, other than AMD. Other disease that could be responsible for decreased vision.
Status: This study is currently recruiting patients.
Information: Eye Care Centre, Vancouver, British Columbia, Canada; Recruiting: Dawn Hay, RN, 604.875.4411 ext. 62544 or Melissa Witzigmann, BSc, 604-875-5285. ■