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

Purpose: AREDS II will evaluate the effect of the two dietary xanthophylls (lutein and zeaxanthin) that accumulate in the macula and two omega-3 long-chain polyunsaturated fatty acids (docosahexaenoic acid and eicosapentaenoic acid) on progression to advanced AMD and/or moderate vision loss in people at moderat- to high-risk for progression.
Sponsor: NEI
Design: AREDS II is a multicenter randomized trial, with a 2 X 2 factorial design.
Number of patients: 4,000
Inclusion/exclusion criteria: Men and women between the ages of 55 and 80 years whose macular status ranges from large drusen in both eyes or large drusen in one eye and advanced AMD (neovascular AMD or geographic atrophy) in the fellow eye are eligible for the study provided that their ocular media are clear enough to allow good fundus photography.
Status: Not yet recruiting. Enrollment is expected to begin in April 2006 and conclude by July 2007.
Information: John Paul SanGiovanni, ScD, division of epidemiology and clinical research, Clinical Trials Branch NEI; phone: 301-496-6583.

Trial: Complications of Age-Related Macular Degeneration Prevention Trial (CAPT)

Purpose: To determine whether application of low-intensity laser treatment of eyes with drusen in the macula can prevent later complications of AMD and thereby preserve visual function.
Sponsor: NEI
Design: Multicenter, prospective, randomized clinical.
Number of patients: N/A
Inclusion/exclusion criteria: Patients must be least 50 years old; vision in each eye must measure 20/40 or better,;at least 10 large drusen in each eye and available for follow-up examinations for 5 years after enrollment. Final eligibility is determined through a detailed eye examination by a CAPT-certified ophthalmologist.
Status: No longer recruiting, study is ongoing.
Information: Natalie Kurinij, PhD, NEI; phone: 301-451-2020.

Trial: A Pilot Study of Laser Photocoagulation for Diabetic Macular Edema

Purpose: This pilot study is not designed for hypothesis testing, but rather for hypothesis generation, for gathering outcome data and for standardization of network protocols.
Sponsor: NEI
Design: Randomized. The study consists of two phases.
Number of patients: N/A
Inclusion/exclusion criteria: Patients must be >18 years of age and have DME involving or threatening the center of the macula and who have not had prior focal/grid laser photocoagulation for DME. Diagnosis of diabetes (type 1 or type 2). No history of renal failure requiring dialysis or renal transplant. Patients in poor glycemic control who recently initiated intensive insulin treatment (a pump or multiple daily injections) or plan to do so in the next 3 months should not be enrolled.
Status: No longer recruiting, study is ongoing.
Information: Jaeb Center For Health Research; phone: 813-975-8690; e-mail: drcrnet@jaeb.org.

Trial: A Pilot Study of Peribulbar Triamcinolone Acetonide for Diabetic Macular Edema

Purpose: This pilot study is being conducted to collect data that can be used to determine whether a phase 3 randomized trial should be conducted, and if it is to be conducted, to provide information to help design the protocol and to estimate sample size.
Sponsor: NEI
Design: Randomized stratified.
Number of patients: Not provided.
Inclusion/exclusion Criteria: Patients must be ≥ 18 years, have a diagnosis of diabetes and at least one eye meets the study eye criteria. A patient is not eligible if he/she has 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 and glycemic control). Patients in poor glycemic control who, within the last 4 months, initiated intensive insulin treatment (a pump or multiple daily injections) or plan to do so in the next 4 months should not be enrolled.
Status: Recruitment is ongoing, the trial is ongoing.
Information: Paivi H. Miskala, MSPH, PhD, NEI; e-mail: miskalap@mail.nih.gov or the Network Chairman's Office, Lloyd P. Aiello, MD, PhD, e-mail: LPAiello@Joslin.Harvard.edu.

Trial: A Randomized Trial Comparing Intravitreal Triamcinolone Acetonide and Laser Photocoagulation for Diabetic Macular Edema

Purpose: To determine whether intravitreal triamcinolone acetonide (Kenalog) injections at doses of 1 mg or 4 mg produce greater benefit, with an acceptable safety profile, than macular laser photocoagulation in the treatment of DME.
Sponsor: NEI
Design: Patients with one study eye will be randomized to one of the three treatment groups.
Number of patients: Not provided.
Inclusion/exlcusion criteria: Patients must be ≥ 18 years

and have diabetes. A patient is not eligible if he or she has a history of chronic renal failure requiring dialysis or kidney transplant.
Status: Recruitment is ongoing, the study is ongoing.
Information: Paivi H. Miskala, MSPH, PhD, NEI; e-mail: miskalap@mail.nih.gov.

Trial: The Standard Care vs Corticosteroid for Retinal Vein Occlusion (SCORE) Study: Two Randomized Trials to Compare the Efficacy and Safety of Intravitreal Injection(s) of Triamcinolone Acetonide with Standard Care to Treat Macular Edema

Purpose: SCORE Study will compare the effectiveness and safety of standard care to intravitreal injection(s) of triamcinolone for treating macular edema associated with CRVO and BRVO.
Sponsor: NEI
Design: Multicenter, randomized, phase 3 trial. Participants will be randomized in a 1:1:1 ratio.
Number of patients: 630
Inclusion/exclusion criteria: Patients with macular edema associated with CRVO and BRVO who are ≥ 18 years and are willing to provide consent may be eligible.
Status: Recruitment is ongoing, study is ongoing.
Information: Maryann Redford, DDS, MPH; e-mail: maryann.redford@nei.nih.gov.

Trial: Cand5 Anti-VEGF RNAi Evaluation (CARE)

Purpose: The trial is studying the use of small-interfering RNA therapy for the treatment of patients with wet AMD.
Sponsor: Acuity Pharmaceuticals
Design: Randomized, double-masked, multicenter trial that includes 3 doses levels of Cand5.
Number of patients: 129 enrolled to date
Inclusion/Exclusion Criteria: N/A
Status: Results are expected midyear.
Information: Acuity Pharmaceuticals: ww.acuitypharma.com.

Trial: RNAi Assessment of Cand5 in Diabetic Macular Edema (RACE)

Purpose: The trial is investigating the safety and preliminary efficacy of Cand5 in DME patients.
Sponsor: Acuity Pharmaceuticals
Design: Pilot phase 2, multicenter, double-masked and randomized trial that will study three dose levels of Cand5.
Number of patients: 48
Inclusion/exclusion criteria: N/A
Status: expected to be completed by the end of 2006
Information: Acuity Pharmaceuticals: ww.acuitypharma.com.

Trial: Intravitreal Steroid Injection Study-Diabetic Macular Edema (ISIS-DME)

Purpose: To evaluate the safety and efficacy of triamcinolone acetonide intravitreal injection.
Sponsor: The Eye Institute of the Medical College of Wisconsin
Design: Six-month prospective, randomized, dose-escalation trial evaluating 2 mg and 4 mg doses of IVTA
Number of patients: 33
Inclusion/exclusion criteria: Macular edema secondary to BRVO, CRVO, postop cystoid macular edema, subfoveal serous pigment epitjeal detachment or juxtafoveal retinal intelangiectasis, >18 years.
Status: Pilot study completed.
Information: Troy Dresher; 414-456-7988 or e-mail: tdresch@mcw.edu.

Trial: Study Of Combined Visudyne Therapy With Kenalog In CNV Secondary To Age-Related Macular Degeneration (VISTA)

Purpose: The primary objective of this study is to determine the effect of Visudyne therapy in combination with 4 mg intravitreal triamcinolone on the mean change in BCVA at month 12.
Sponsors: Manhattan Eye, Ear & Throat Hospital, Novartis, QLT
Design: N/A
Number of Patients: 120
Inclusion/exclusion criteria: Age ≥ 50 years, subfoveal CNV secondary to AMD, area of the CNV at least 50% of the area of the total neovascular lesion, the lesion is either minimally classic or occult with no classic. If the lesion is occult with no classic then subjects must have presumed recent disease progression in the study eye in the judgment of the investigator and as defined by presence of blood associated with the lesion or vision loss or lesion growth reported or objectively recorded within the preceding 3 months before randomization to treatment. Baseline BCVA score between 73 and 19 letters on the ETDRS scale (approximately 20/40 to 20/400). Lesion size <5400 µm.
Status: This study is currently recruiting patients. Completion is expected in January 2007.
Information: Namrata Saroj, OD: 212-605-3777 or e-mail: nsaroj@retinal-research.org.

Trial: A Safety and Efficacy Study of Squalamine Lactate for Injection (MSI-1256F) for "Wet" Age-Related Macular Degeneration

Purpose: The trial objective is to evaluate the safety and efficacy of two doses of Squalamine lactate for Injection administered as intravenous infusions weekly for 4 weeks followed by maintenance doses every 4 weeks through week 104 compared with the safety and efficacy in the control group.

Sponsor: Genaera
Design: Interventional, randomized, double-masked, placebo-controlled, parallel-assignment, safety/efficacy study, phase 3.
Number of patients: Not provided.
Inclusion/Exclusion criteria: Patients with a diagnosis of wet age-related macular degeneration. Excluded are patients with treatment for wet age-related macular degeneration in the affected eye in the past 3 months
Inclusion/exclusion criteria: N/A
Status: The expected completion is June 2008. The study is recruiting patients.
Information: Jamila Watkins: 800-299-9156 or e-mail: jwatkins@genaera.com.

Trial: Macugen (Pegaptanib Sodium) Alone, Versus Macugen in Combination With PDT With Visudyne in Patients With AMD

Purpose: The purpose of the trial is to compare whether pegaptanib sodium in combination with PDT with verteporfin is safe and effective in slowing down the leakage of fluid within the eye and thereby stabilizing or improving vision when compared with pegaptanib alone.
Sponsor: Eyetech Pharmaceuticals and Pfizer
Design: Phase 4, randomized, double-masked, active control, parallel-assignment, safety/efficacy study.
Number of patients: 360
Inclusion/exclusion criteria: Patients of either gender; aged ≥ 50 years, subfoveal CNV due to AMD with predominantly classic lesion composition, BCVA in the study eye between 20/40 and 20/200. Exclusion criteria: Any prior PDT with verteporfin to the study eye, any previous AMD thermal laser therapy to the study eye.
Status: This study is currently recruiting patients; the expected completion is October 2008.
Information: Call 866-622-8436.

Trial: Clinical Study Of EYE001 For Wet-Type AMD

Purpose: This study will examine the efficacy and safety of pegaptanib sodium in Japanese patients with wet-type 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: Wet 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: Study of AdGVPEDF.11D in Neovascular AMD

Purpose: The primary purpose of this study is to assess the safety of AdGVPEDF.11D when given to patients with "wet" AMD. AdGVPEDF.11D is a replication deficient (E1, E3 and E4 deleted) adenovirus vector containing the gene for the PEDF (pigment epithelium-derived factor) protein.
Sponsor: GenVec
Design: Phase 1, treatment, open-label, dose-comparison, safety study.
Number of patients: Not provided.
Inclusion/exclusion criteria: Age ≥ 50 years; severe neovascular AMD in at least one eye responsible for a BCVA of 20/200 or worse in the study eye (if both eyes have neovascular AMD and equal visual acuity scores, the study eye will be determined by the investigator); BCVA in the fellow eye must be equal to or better than the study eye; fluorescein angiography of the study eye must show evidence of a leaking subfoveal choroidal neovascular lesion. The subfoveal component must consist of CNV blood or fibrosis. The total size of the lesion must be ≤ 12 MPS disc areas. The presence of a leaking subfoveal choroidal neovascular lesion will be evaluated by the investigator at the clinical site to determine patients' eligibility. Patients must not be candidates for (including patients who have had treatment with either modality in the past and are no longer candidates) or must have refused treatment with subfoveal laser photocoagulation or PDT; able to comply with protocol requirements including follow-up visits. Exclusion criteria: liver enzymes > 2 x ULN (ALT, AST, bilirubin); clinical evidence of active infection of any type, including adenovirus, hepatitis A, B, or C virus or HIV virus; other treatment for AMD in the study eye within the last twelve weeks prior to day 1; other experimental medications within the last 4 weeks prior to day 1; significant retinal disease other than neovascular AMD, such as diabetic retinopathy or retinal vascular occlusion; significant nonretinal disease such as ocular atrophy; cataract or other significant media opacity that might compromise examination and photography of the posterior segment; other causes of choroidal neovascularization such as pathologic myopia (>8 D), ocular histoplasmosis or angioid streaks; evidence of inflammation (≥ grade 1) in the anterior and/or posterior chambers; cataract surgery or submacular surgery within 3 months; prior ocular treatment with radiation; known allergy to fluorescein; abnormal prothrombin or partial thromboplastin time (>1.5 X ULN) or anticoagulant therapy that cannot be withheld for treatment.
Status: This study is currently recruiting patients.
Information: Contact Rosaleen Ostrick at the UCLA - Jules Stein Eye Research Center, Los Angeles; 310-794-5595 or e-mail: ostrick@jesi.ucla.edu.

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 for treatment of wet 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 photodynamic therapy. (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 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: N/S
Inclusion/exclusion: Wet AMD, size of the lesion (if predominantly classic type) must be ≤ 5400 microns. 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 (measured with a special chart). 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: TTT Versus PDT for Treatment of Choroidal Neovascularization in Age-Related Macular Degeneration

Purpose: The purpose of the study is to compare PDT to transpupillary thermotherapy as a treatment method for choroidal neovascularization in AMD.
Sponsor: St. Erik Eye Hospital
Design: Treatment, randomized, single blind, active control, parallel-assignment, efficacy study
Number of patients: 140
Inclusion/exclusion: N/A
Status: Expected completion is April 2008. Patients are no longer being recruited.
Information: Anne C. Odergren, MD; +46 8 6723000 ext. 3066; e-mail: anne.odergren@sankterik.se

Trial: A Phase 2 Study of Implants of Encapsulated Human NTC-201 Cells Releasing Ciliary Neurotrophic Factor (CNTF) in Participants with Visual Acuity Impairment Associated with Atrophic Macular Degeneration

Purpose: This is an 18-month study to evaluate the safety and effectiveness of ciliary neurotrophic factor (CNTF) implants on vision in participants with atrophic macular degeneration.
Sponsor: NEI
Design: Treatment, safety/efficacy, phase 2.
Number of patients: 36
Inclusion/exclusion criteria: See www.clinicaltrials.gov for comprehensive listing.
Status: Study began January 6.
Information: NEI: 800-411-1222; or e-mail: prpl@mail.cc.nih.gov

Trial: Efficacy and Safety of Ranibizumab 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: N/A
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

Study: Triamcinolone Acetonide Plus Laser Therapy to Treat Age-Related Macular Degeneration

Purpose: This study will test the safety and effectiveness of combining PDT, with injections of the steroid triam-

cinolone acetonide for treating AMD.
Sponsor: NEI
Design: Treatment, efficacy, phase 3.
Number of patients: 300
Inclusion/exclusion criteria: See compehensive listing at www. clinicaltrials.gov.
Status: This study is currently recruiting patients.
Information: NEI Patient Recruitment and Public Liaison Office: 800-411-1222 or e-mail: prpl@mail.cc.nih.gov.

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 geographic atrophy and/or choroidal neovascularization 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: A Study to Evaluate Ranibizumab in Subjects With CNV Secondary to AMD

Purpose: This is a Phase 3b, single-masked, 1-year multicenter study of the safety and tolerability of intravitreally administered ranibizumab in subjects with active subfoveal CNV secondary to AMD.
Sponsor: Genentech
Design: Phase 3b, single-masked, multicenter, randomized.
Number of patients: 5,000
Inclusion/exclusion criteria: For treatment-naive patients: newly diagnosed, previously untreated, active subfoveal CNV lesions secondary to AMD. For previously treated patients: previous diagnosis and treatment of CNV secondary to AMD, currently active CNV lesions, a loss of ≥ 5 ETDRS letters (or ≥ 1 Snellen line) in BCVA over the last 6 months, and a minimum 30-day washout since previous treatment. Total lesion area ≤ 12 disc areas (DA) in size BCVA, using ETDRS charts, of 20/40 to 20/320 (Snellen equivalent) in the study eye. Only one eye will be assessed in the 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. (See www.clinicaltrials.gov for comprehensive lisitng of exclusion criteria.)
Status: This stud y is recruiting patients.
Information: Call Trial Information Support Line at 888-662-6728.

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. Best corrected visual acuity 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 panretinal photocoagulation. Prior treatment with an investigational agent for DME.
Status: This study is currently recruiting patients. Expected completion is February 2010.
Information. Call 866-622-8436.

Trial: High-Resolution Ultrasound Imaging of the Retina and Choroid for Detection on Age Related Macular Degeneration

Sponsors: Weill Medical College of Cornell University and the American Institute of Ultrasound in Medicine

Purpose: This study will investigate use of high frequency (20 MHz) ultrasound for imaging of the retina and choroid in patients with age-related macular degeneration, a prime cause of blindness. The investigation will involve use of novel post-processing methodologies to achieve maximum resolution of the fine tissue structures involved in this disease.
Design: Observational, screening, cross-sectional, defined population, retrospective/prospective study.
Number of patients: 40
Inclusion/exclusion criteria: Age related macular degeneration age matched control.
Status: This study is currently recruiting patients. the completion date is June 2006.
Information: Harriet O Lloyd, MS, 212-746-6106; e-mail: hlloyd@med.cornell.edu; or Ronald H. Silverman, PhD, 212-746-6106; e-mail: ros2012@med.cornell.edu.

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 on retinal edema and visual acuity in patients with diabetic macular edema 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: Diabetic macular edema 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: 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) 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: Internal Limiting Membrane Peeling for Large Macular Holes

Purpose: To show that the percentage of success (anatomical closing, confirmed by OCT) at third post-operative month is higher in the ILM peeling group.
Sponsor: Assistance Publique - Hôpitaux de Paris
Design: Randomized monocentric study, in parallel groups, open label, active control, parallel assignment, bio-equivalence study.
Number of patients: 80, expected completion March 2008.
Inclusion/exclusion criteria: Older than 18 years, presenting with macular hole >400 µm. Patient having been informed of the objectives and constraints of the study and having signed an informed consent.
Status: This study is currently recruiting patients.
Information: Ramin Tadayoni, MD, +33(0)1 49 95 64 88; e-mail: ramin.tadayoni@lrb.aphp.fr.

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. ■