

DATE: March 1, 2015

SUBJECT: CURRENT ENROLLING CLINICAL STUDIES FOR WEB SITES

Enrolling Clinical Studies being conducted at the Department of Ophthalmology, ACC Building, Suite 2400

Glaucoma

1. Title: Baerveldt Plate Area Comparison (BPAC)
PI: James D. Brandt, MD
Protocol #: 271065
Sponsor: Department of Ophthalmology in collaboration with Johns Hopkins Hospital and Glaucoma Research Network
Purpose: The objective of this study is to compare the safety and efficacy of the 250 mm² and 350 mm² Baerveldt glaucoma implants in subjects who have had previous ocular surgery. Outcome discrimination between the two treatment groups will be made using measures of visual function (visual acuity and visual field), IOP, need for supplemental medical therapy, surgical complications, and reoperation for glaucoma or complications.
Indications: Patients between the ages of 18 and 85 years with inadequately controlled glaucoma who may have had prior intraocular surgery
Coordinator: Katrina Imson, Sr. CRC, 734-6814

2. Title: Evaluation of Optic Nerve Structure and Function in Patients with Keratoprosthesis
PI: Michele C. Lim, MD
Protocol #: 223055
Sponsor: Department of Ophthalmology & Vision Science
Purpose: To better understand how to monitor patients with a Boston keratoprosthesis (K-pro) for optic nerve damage from glaucoma through optic nerve photography, spectral-domain OCT, kinetic visual fields, and Humphrey visual fields. Patients with a K-pro are at high risk for developing glaucoma and it is difficult to measure eye pressure (IOP) in these patients due to the rigid plastic material from which the K-pro is made. Therefore, finding other measures to evaluate patients with a keratoprosthesis are necessary.
Indication: Patients with a Boston keratoprosthesis
Coordinators: Katrina Imson, Sr.CRC, 734-6814

Cornea

- 3 Title: A Prospective, Multicenter Post-Approval Study (PAS) of VisionCare's Implantable Miniature Telescope (by Dr. Isaac Lipshitz) in Patients with Bilateral Severe to Profound Central Vision Impairment Associated with End-Stage Age-Related Macular Degeneration (Telescope Study)
PI: Jennifer Li, MD
Protocol # 445488
Sponsor: VisionCare Ophthalmic Technologies
Purpose: To evaluate the safety of the Implantable Miniature Telescope (intraocular telescope) for the treatment of bilateral severe to profound vision impairment due to end stage age-related macular degeneration under commercial conditions following U.S. market approval. To further assess the safety of the intraocular

telescope as measured by the proportion of patients who within 5 years after implantation experience persistent vision-impairing corneal edema (corneal edema leading to a persistent loss of best corrected distance visual acuity [BCDVA] > 2-lines from pre-surgery baseline level).

Indication: Patients with end stage age-related macular degeneration including geographic atrophy or disciform scar with foveal involvement; visually significant cataract.

Coordinator: Katrina Imson, Sr. CRC, 734-6814

Retina

4. Title: Study of Ocular Fluid, Serum and Urine for Biomarkers of Eye Disease in Patients
- PI: Lawrence S. Morse, MD, PhD
- Protocol # 216607
- Sponsor: Departments of Ophthalmology & Vision Science, and Endocrinology
- Purpose: 1) To determine if there is a concentration gradient for each biomarker studied between the aqueous and the vitreous humors.
- a. To determine if the concentration gradient for each biomarker studied between the aqueous and vitreous humor depends on whether the patient is phakic or pseudophakic.
 - b. To determine if there is any correlation between the concentration of biomarkers in serum and ocular fluids.
 - c. -To determine if there is any correlation between the concentration of these biomarkers and diabetes control and complications related to diabetes.
- 2) To determine the presence of specific biomarkers for retinal disease in serum,urine or ocular fluids.
- a. -To establish a normal database of the signaling molecules and biomarkers in serum,urine, aqueous and vitreous humor of patients with known retinal disease and correlate this with levels from normal patients without retinal or ocular disease.
 - b. -To better understand retinal disease based on the molecular signals in ocular fluids.
- Indication: Patients 18 years of age and older who are scheduled for an ocular procedure during which vitreous and aqueous humor normally discarded is collected.
- Coordinators: Marisa Salvador, CRC, 734-6302, and Cindy Wallace, Sr. CRC 734-6393
5. Title: A Phase III, Multinational, Multicenter, Randomized, Double-Masked, Study Assessing the Safety and Efficacy of Intravitreal Injections of DE-109 (three doses) for the Treatment of Active, Non-Infectious Uveitis of the Posterior Segment of the Eye
- PI: Lawrence S. Morse, MD, PhD
- Protocol # 350350
- Sponsor: Santen, Inc.
- Purpose: The primary purpose of the trial is to evaluate the safety and efficacy of intravitreal injection of three doses of DE-109 (44 µg, 440 µg, 880 µg) for the treatment of active, non-infectious uveitis of the posterior segment of the eye. Additional trial objectives are to evaluate: · The long term safety of multiple intravitreal injections of 880 µg dose of DE-109 beyond Mo. 5. Also, the durability of effect of 880 µg dose(s) of DE-109.
- Indication: Patients 18 years of age or older with active uveitis of posterior segment determined to be non-infectious, with vision ≥ 20/200 in the non-study eye.
- Coordinator: Cindy Wallace, Sr. CRC, 734-6393

6. Title: Phase 1/2 Randomized Prospective Double-Blinded Trial Comparing Intravitreal Administration of Inhibitors of Vascular Endothelial Growth Factor Combined with Proton Beam Irradiation versus Intravitreal Administration of Vascular Endothelial Growth Factor Combined with Sham Irradiation in Treating Exudative Age-related Macular Degeneration
- PI: Susanna S. Park, MD, PhD
 Protocol #: 223071
 Sponsor: Dr. Park and Department of Ophthalmology & Vision Science
 Purpose: The specific aim of the study is to test the hypothesis that low dose proton beam irradiation combined with intravitreal administration of inhibitor of vascular endothelial growth factor (anti-VEGF) is safe and more effective than treatment with anti-VEGF alone in treating exudative age-related macular degeneration (eAMD). Specifically, the Primary Objective of this study is to determine the safety and efficacy of proton beam radiation combined with ranibizumab (Lucentis) or bevacizumab (Avastin) in treating patients with exudative AMD.
- Indication: Patients 50 years of age or older with “wet” age-related macular degeneration.
 Coordinator: Katrina Imson, Sr.CRC, 734-6814
7. Title: A Pilot Clinical Trial of the Feasibility and Safety of Intravitreal Autologous Adult Bone Marrow Stem Cells in Treating Eyes with Vision Loss from Retinopathy
- PI: Susanna S. Park, MD, PhD
 Protocol #: 305805
 Sponsor: Dr. Park and Department of Ophthalmology & Vision Science
 Purpose: This proposed pilot study is to investigate the feasibility and safety of intravitreal autologous Bone Marrow Stem Cell therapy in treating people with irreversible vision loss from retinal degenerative conditions or retinal vascular disorders. Fifteen subjects with vision loss that meet the inclusion and exclusion criteria of this study will be injected intravitreally with autologous CD34 positive BMSCs.
- Indication: Patients 18 years of age or older with 20/100 to Count Fingers visual acuity; vision loss due to “dry” age-related macular degeneration, retinitis pigmentosa, retinal vein occlusion, diabetic retinopathy, and hereditary maculopathy.
 Coordinator: Marisa Salvador, CRC, 734-6302
8. Title: Study of COmparative Treatments for REtinal Vein Occlusion 2 (SCORE2): a multicenter, prospective, randomized non-inferiority trial of eyes with macular edema secondary to central retinal vein occlusion, comparing intravitreal bevacizumab every 4 weeks with intravitreal aflibercept every 4 weeks.
- Short Title: Study of Comparative Treatments for Retinal Vein Occlusion 2 (SCORE2)
 PI: Susanna S. Park, MD, PhD
 Protocol #: 610600
 Sponsor: National Eye Institute / Penn State University
 Purpose: This study will compare the drugs aflibercept (Eylea®) and bevacizumab (Avastin®) for treatment of macular edema (swelling in the center of the retina) due to central retinal vein occlusion (CRVO). If the drug the subject is randomized to is ineffective for the first 6 months, the subject may be given dexamethasone or switched to another anti-VEGF treatment. All drugs in this study have already been approved by the FDA.
- Indication: Patients 18 years of age or older with center-involved macular edema secondary to CRVO.
 Coordinator: Cindy Wallace, Sr.CRC, 734-6393

9. Title: Ocriplasmin Research to Better Inform Treatment (ORBIT)
 PI: Ala Moshiri, MD, PhD
 Protocol #: 652041
 Sponsor: ThromboGenics
 Purpose: This study will observe the clinical outcomes and safety in patients receiving JETREA® for the treatment of symptomatic vitreomacular adhesion (VMA) as per standard of care in US retina clinics for a follow-up period of up to 12 months.
 Indication: Patients 18 years of age or older diagnosed with symptomatic VMA treated with JETREA®.
 Coordinator: Marisa Salvador, .CRC, 734-6302
10. Title: A Phase III, Multicenter, Randomized, Double-Masked, Sham-Controlled Study to Assess the Efficacy and Safety of Lampalizumab Administered Intravitreally to Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration – Protocol GX29185/SPECTRI
 PI: Lawrence S. Morse, MD, PhD
 Protocol #: 679052
 Sponsor: Genentech / F.Hoffmann-La Roche Ltd.
 Purpose: To assess the efficacy and safety of 10-mg lampalizumab administered by intravitreal injections every 4 weeks (Q4W) or every 6 weeks (Q6W) relative to sham control for the treatment of Geographic Atrophy secondary to Age-Related Macular Degeneration. Efficacy, safety, and PK will be evaluated in CFI profile biomarker-positive and CFI profile biomarker-negative patients.
 Indication: Patients 50 years of age or older with Geographic Atrophy secondary to Age-related Macular Degeneration in both eyes
 Coordinator: Cindy Wallace, Sr.CRC, 734-6393

Studies being conducted at Department of Ophthalmology Cadillac Dr. Clinic, 77 Cadillac Dr., Sacramento

11. Title: Pediatric Cataract Surgery Registry (CO2 Study)
 PI: Mary O'Hara, M.D.
 Protocol #: 573697
 Sponsor: National Eye Institute / Jaeb Center for Research
 Purpose: The specific aim of the proposed research is to learn about cataract surgery in children. The study involves the collection of information about children who have had cataract surgery. This is a data collection study only.
 Indication: Children birth to 13 years of age who have undergone cataract surgery in at least one eye. Data will be collected over a 3-year period.
 Coordinator: Tania Hashmi, Coordinator, 734-4641

Visual Psychophysics Laboratory

12. Title: Ophthalmic Imaging Using Adaptive Optics and Optical Coherence Tomography
 PI: John S. Werner, PhD.
 Protocol#: 223362
 Sponsor: National Institute for Aging & National Eye Institute
 Purpose: To learn more about how vision and retinal structure change with age and/or disease
 Indication: Males and females age 50 years and older with normal eyes, or males and females with one age-related macular degeneration.
 Coordinator: Susan Garcia, COT, CRC, 734-4546

13. Title: Temporal Impulse Response Changes Across the Life Span
PI: John S. Werner, PhD.
Protocol#: 230420
Sponsor: National Institutes of Health
Purpose: To learn more about age-related changes in the ability to detect flicker or movement
Indication: Males and females age 18 years and older with normal eyes
Coordinator: Susan Garcia, COT, CRC, 734-4546
14. Title: Age-Related and Disease-Related Changes in the Photopic and Scotopic Full-Field and Multifocal ERGs
PI: John S. Werner, PhD.
Protocol#: 218967
Sponsor: National Institutes of Health
Purpose: To learn more about how the response of the retina changes with age and a disease affecting central vision called "Age-Related Macular Degeneration" (AMD)
Indication: Males and females age 18 years and older with normal eyes or with AMD
Coordinator: Susan Garcia, COT, CRC, 734-4546