Prospective Retinal and Optic nerve Vitrectomy Evaluation (PROVE) Study

PI: Stephen Jae Kim M.D.

**Primary Objective:**

To determine the incidence of nerve fiber layer (NFL) and macular changes after pars plana vitrectomy, characterize their extent and quality, and determine pre-disposing risk factors.

**Major Inclusion Criteria:**

1. No previous treatment or surgery that might confound study result in the study or fellow eye
2. The need for pars plana vitrectomy due to macular pucker, macular holes, vitreomacular traction and vitreous opacity

**Major Exclusion Criteria:**

1. History of glaucoma and visual field defect
2. Advanced diabetic retinopathy and previous retinal detachment in the control eye
3. Previous vitrectomy, bilateral disease, any condition that may result in choroidal neovascularization in the control eye
Incidence of Increase Intraocular Pressure After Pars Plana Vitrectomy

PI: Stephen Jae Kim, M.D.

Objectives:
The purpose of this research is to analyze and compare long-term intraocular pressure (IOP) trends and risk of glaucoma in eyes after pars plana vitrectomy with their non-operated fellow eyes.

Inclusion Criteria:
All adult patients (> 18) without prior vitrectomy

Exclusion Criteria:
Patients with preexisting ocular disorder with known risk of glaucoma (retinopathy of prematurity, congenital cataract, persistent fetal vasculature, etc), proliferative diabetic retinopathy, less than 6 months of follow-up, or are undergoing vitrectomy due to trauma, retinal detachment (rhegmatogenous, serous, tractional), uveitis, or infection (endophthalmitis).

Intravitreal Ketorolac for Chronic Inflammation and Retinal Edema (INCITE) Study

PI: Stephen Jae Kim M.D.

Objectives:
The purpose of this study is to test the safety and effectiveness of intraocular injection of ketorolac to treat chronic inflammation and other complications such as macular edema.

Inclusion Criteria:
1. Twenty eyes of 20 adult volunteers
2. Chronic intractable uveitis or chronic complications of uveitis (macular edema) despite maximal medical treatment
3. Unable to tolerate corticosteroids due to side effects

Exclusion Criteria:
1. 18 years or younger
2. Have active ocular infection
3. Pregnancy
Investigation of Genes that Cause Primary Congenital Glaucoma (PCG Study)

PI: Rachel Kuchtey, M.D., Ph.D.

Objective:
The purpose of this study is to identify the genetic defect involved in primary congenital glaucoma (PCG). Although PCG is very rare, the knowledge gained from this study may potentially help us understand the cause of other common forms of glaucoma.

Inclusion Criteria:
1. Patients with established diagnosis of PCG
2. Ages 0 to 90 years

Exclusion Criteria:
Glaucoma secondary to other identifiable eye/systemic diseases

Investigation of Genes that Cause Adult-onset Primary Open-angle Glaucoma (POAG)

PI: Rachel Kuchtey, MD, Ph.D.

Objective:
The purpose of this study is to help us learn if we can identify genes that can be linked to glaucoma. If the doctors can identify a genetic cause of glaucoma it may lead to improvement in evaluation and treatment options for patients.

Inclusion Criteria:
1. Patients with established diagnosis of POAG
2. Patients with cataract, but free of POAG as control
3. Ages 20 to 90 years

Exclusion Criteria:
Glaucoma secondary to other identifiable eye/systemic diseases

A Pilot Study in Individuals with Center-Involved DME Undergoing Cataract Surgery (Protocol P)

PI: Franco Recchia, M.D.

Objective:
1. To determine the feasibility of a randomized trial in eyes with center-involved DME prior to cataract surgery.
2. To describe how cataract surgeons and Diabetic Retinopathy Clinical Research (DRCR) Network investigators manage these cases at the time of surgery and to evaluate exacerbation of diabetic macular edema and visual acuity at 6 weeks.

Major Eligibility Criteria:
1. Age >=18 years
2. Type 1 or type 2 diabetes
3. Planned cataract extraction
**An Observational Study in Individuals with Diabetic Retinopathy without Center-involved DME Undergoing Cataract Surgery (Protocol Q)**

**PI: Franco Recchia, M.D.**

**Objectives:**
The objective of the study is to determine the incidence of progression to center-involved macular edema 16 weeks after cataract surgery in eyes with diabetic retinopathy and without definite center-involved DME.

**Major Eligibility Criteria:**
1. Age ≥18 years
2. Type 1 or type 2 diabetes

**Major Exclusion Criteria**
1. Subject must remain in the clinical center area during the 16 weeks of the study.
2. An investigator may determine that there is an ocular condition present that affects visual acuity and excludes subject from the trial.
3. History of major ocular surgery within prior 4 months or major ocular surgery other than cataract anticipated within the next 4 months following enrollment.

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**Evaluation of Illuminated Low Vision Glasses: Quality of Life Outcomes and Reading Speed**

**PI: Jeffrey Sonsino, O.D., F.A.A.O.**

**Objectives:**
Compare subjects near visual acuity, time to fatigue, reading speed and activity inventory using Illuminated Low Vision Glasses to those with habitual reading glasses. Task performance measures will be administered in the office and after subjects use Illuminated Low Vision Reading Glasses for 2 weeks.

**Inclusion Criteria:**
1. Ages 50-100.
2. Best-corrected visual acuity of 20/50 to 20/100 in the better seeing eye. This is the generally agreed upon definition of low vision
3. Ocular diseases including age-related macular degeneration, glaucoma, diabetic retinopathy, cataract, Stargart maculopathy.

**Exclusion Criteria:**
1. Subject with refractive errors of -3.00D or higher myopia or +2.00D or higher hyperopia.
2. Subjects with greater than -2.00D of astigmatism
3. Subjects with any ocular disease with photophobia
**Antioxidant Systems and Age-Related Macular Degeneration**

**PI: Paul Sternberg, M.D.**

**Objectives:**

The purpose of this study is to find out if there are changes in blood that would be considered risk factors for having age related macular degeneration. Blood samples will undergo a battery of tests exploring different potential markers for this disease. In addition, this study will explore how these markers are impacted by the antioxidant supplements currently used to treat patients with AMD, through a one week stay at the Clinical Research Center.

**Inclusion Criteria:**
1. Age 55 to 80 years
2. Patients will be included that would fulfill the AREDS criteria for intermediate or advanced AMD (Groups 3 and 4). Fundus photographs will be taken in the physicians’ office and sent to the Vanderbilt Ophthalmic Imaging Center for grading.
3. Age-matched patients without AMD will be enrolled as control subjects.

**Exclusion Criteria**
1. Patients who do not have at least intermediate drusen in both eyes.
2. Patients with diabetes

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**A Multi-Center, Prospective, Observational Study of the PRogression Of Ocular Findings in Patients with Dry Eye Disease (MA-RES-08-001) (PROOF)**

**PI: Uyen Tran, M.D.**

**Objectives:**

The purpose of this study is to develop a better understanding of the natural history of dry eye.

**Major Eligibility Criteria:**
1. Males > 55 years old or females > 40 years old with perimenopausal symptoms or post menopausal.
2. Moderate to severe dry eyes as defined by:
   - Baseline OSDI score of > 13 and level 2 ITF consensus
   - Schirmer's test (with anesthesia) ≤ 7mm
3. Best corrected visual acuity in at least one eye of 20/80 or better.

**Major Exclusion Criteria:**
1. Use of any topical cyclosporine ophthalmic emulsion within 3 months of baseline.
2. History of herpes keratitis or varizella zoster keratitis.
3. Any history of allergic conjunctivitis.
4. Temporary or permanent occlusion or cauterization of the lacrimal puncta for either eye.
5. Use of or planned use of topical glaucoma medications during the study.
6. Any anterior segment surgery involving a limbal or corneal incision (cataract surgery), keratorefractive procedure (LASIK, LASEK, PRK), or trauma which could have an impact on corneal sensitivity within the last 12 months or expectation of such surgery within 2 years.
7. Any history of penetrating keratoplasty (corneal transplant).