Trial: Full Thickness Macular Hole (FTMH) and Internal Limiting Membrane (ILM) Peeling Study

Purpose: The aim of this study is to determine whether, in patients with a stage 2 or 3 FTMH, peeling the internal limiting membrane (ILM) during surgery is superior to non-ILM peeling macular hole surgery. The main outcomes are improvement in vision, achievement of macular hole closure, need for reoperation, health related quality of life and cost-effectiveness.
Sponsor: University of Aberdeen
Design: Treatment, randomized, single-masked, active-control, parallel-assignment, efficacy study.
Number of patients: 150
Inclusion/exclusion criteria: Idiopathic FTMH of stage 2-3, duration of hole ≤18 months, visual acuity equal to or worse than 20/40 in the study eye. Eclusion criteria:Stage 1 or 4 FTMH, stage 2-3 FTMH of >18 months duration, visual acuity >20/40 in study eye, FTMH related to high myopia (>6 D), FTMH related to trauma, any other causes of decreased vision (ie, corneal scarring, age-related macular degeneration [AMD], diabetic retinopathy, glaucoma if central and/or paracentral absolute visual field defects present), patient unable to understand English, patient unable to give informed consent.
Status: This study is currently recruiting patients.
Information: Contact Noemi Lois at noemilois@aol.com or Alison M McDonald at a.mcdonald@abdn.ac.uk or visit www.charttrials.abdn.ac.uk/films/.

Trial: Alleviated Positioning for Small Macular Holes

Purpose: To show that the percentage of success (anatomical closure confirmed by optical coherence tomography [OCT]) is not lower in the group without positioning.
Sponsor: Assistance Publique - Hôpitaux de Paris.
Design: Treatment, randomized, open-label, active-control, parallel-assignment, efficacy study.
Number of patients: 68
Inclusion/exclusion criteria: Age ≥18 years, patient presenting an idiopathic macular hole of stage 2, 3 or 4, opening diameter of the macular hole ≤400 µm, patient having been informed of the objectives and constraints of the study and having signed an informed consent, patient not presenting a per-operational complication having required a complementary gesture or a modification of the usual procedure, with the only exception of discovering a retinal tear, flat, located between 10 o'clock and 2 o'clock and having required only a treatment by cryo.
Status: This study is currently recruiting patients.
Information: Contact Ramin Tadayoni, MD, at ramin.tadayoni@lrb.aphp.fr or +33 (0) 1 49 95 64 88.

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, with individual benefit for the patient.
Number of patients: 80
Inclusion/exclusion criteria: Age equal to or higher than 18 years, patient presenting idiopathic of stage 2, 3 or 4, macular hole >400 µm in diameter, 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: Contact Ramin Tadayoni, MD, at ramin.tadayoni@lrb.aphp.fr or +33 (0) 1 49 95 64 88.

Trial: A Phase II 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 CNTF implants on vision in participants with atrophic macular degeneration.
Sponsor: National Eye Institute (NEI)
Design: Randomized, interventional
Number of patients: 36
Inclusion/exclusion criteria: To participate in this study, the 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). Women of childbearing potential and all men must agree to use an effective form of birth control from study onset until 6 months postexplant. Participant medically able to undergo ophthalmic surgery for device implant. BCVA in the study eye less than 20/63 to 20/160. History of a decrease in visual acuity in the study eye within the last 5 years as assessed by a vision test. Presence in the study and/or fellow eye of geographic atrophy (GA) compatible with category 3 or 4 AMD as defined by Age-Related Eye Disease Study (AREDS). Also, the GA in the study eye must be associated with vision loss as assessed by

a vision test. GA is defined as one or more well-defined, usually more or less circular patches of partial or complete depigmentation of the retinal pigment epithelium (RPE), typically with exposure of underlying choroidal blood vessels. 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 at least 175 µm in area. Participant must have steady fixation in the study eye in the foveal or parafoveal area and media clear enough for good quality photographs. Exclusion criteria: Participant less than 50 years of age (to minimize geographic atrophy from causes other than AMD). Participant 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 (eg, equal to 4 weeks at a time) 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 classic or occult choroidal neovascularization in either eye, which may include serous RPE detachment, stippling on a fluorescein angiogram, macular edema, evidence of hemorrhage and lipid, and disciform scar. Participant has evidence of central serous chorio-retinopathy in either eye. Participant has evidence of pathologic myopia in either eye. Participant has evidence of pseudovitelliform macular degeneration (a dominantly inherited disease characterized by a round or oval yellow subretinal macular deposit) in either eye. Participant with evidence of vitreo-retinal traction maculopathy in either eye. Participant has a history of laser, photodynamic therapy, intravitreal injection of anti-vascular endothelial growth factor agent, or any previous treatment for AMD other than AREDS or equivalent supplement formulation. Participant has had a vitrectomy, penetrating keratoplasty, trabeculectomy or trabeculoplasty. Participant who has any of the following lens opacities: cortical opacity greater than standard 3, posterior subcapsular opacity greater than standard 2, or a nuclear opacity greater than standard 3 as measured on the AREDS clinical lens grading system. Participant has undergone lens removal in the last 3 months. Participant has participated in any other clinical trial of a drug or device within the last 6 months. Participant is on chemotherapy.
Participant is on ocular or systemic medications known to be toxic to the lens, retina, or optic nerve. Participant is pregnant or lactating. Participant has other retinal disease(s).
Participant with history of malignancy that would compromise the 2-year study survival.
Participant is considered immunodeficient or has a known history of HIV. Participant with a history of ocular Herpes simplex virus.
Status: This trial is currently recruiting patients.
Information: Contact prpl@mail.cc.nih.gov.

Trial: Trial of Prognostic Factors and Surgical Methods for the Treatment of Idiopathic Macular Holes

Purpose: Data analyses will help clarify the effect of ILM peeling on hole closure and visual acuity.
Sponsor: Herlev Hospital, Danish Eye Health Society and The Danish Medical Research Council.
Design: Treatment, randomized, double-blind, active-control, parallel-assignment, efficacy study
Number of patients: 80
Inclusion/exclusion criteria: Idiopathic macular hole stage 2 or 3, duration of symptoms ≤12 months, visual acuity ≥34 Early Treatment of Diabetic Retinopathy Study (ETDRS) letters, intraocular pressure ≤23 mmHg and informed consent. Exclusion citeria: Previous macular hole in project eye, macular pucker worse than a cellophane macular reflex, previous surgery or disease in the eye affecting retinal function, systemic disease affection vision including diabetes mellitus with level of retinopathy ≥14a or amblyopia in project eye.
Status: This study is currently recruiting patients.
Information: Contact Ulrik Christensen, MD, at ulrikchristensen@dadlnet.dk or +45 44884657; or Kristian Kroyer, MD, kroyer@dadlnet.dk or +45 44884302.

Trial: Effect of Prophylactic Ketorolac on CME After Cataract Surgery

Purpose: The study will evaluate the efficacy of prophylactic administration of the topical nonsteroidal anti-inflammatory drug (NSAID) ketorolac tromethamine 0.5% (Acular; Allergan, Irvine, Calif) on cystoid macular edema (CME) in patients having undergone cataract surgery. CME is the most frequent cause of decreased vision after uncomplicated cataract surgery and can result in irreversible sight reduction. The investigation will involve a comparison arm and a treatment arm with both sets of patient populations being evaluated for CME with ophthalmologic examinations and OCT measurements. The objective is to elucidate the role of NSAID drops in preventing CME after cataract surgery.

Sponsor: Queen's University
Design: Prevention, randomized, open-label, placebo-control, single-group assignment
Number of patients: 100
Inclusion/exclusion criteria: First cataract surgery (ie, first eye). Exclusion criteria: any preexisting retinal/macular disease, ocular tumours, uveitis, hypersensitivity to the NSAID drug class, pregnancy or previous intraocular surgery.
Status: This trial is recruiting patients.
Information: Contact Sherif El-Defrawy, MD, PhD, FRCS(C) at sre1@post.queensu.ca or 613-544-3400 Ext. 2225.

Study: Tissue Studies of Human Eye Diseases

Purpose: The purpose of this study is to better understand the processes involved in the development of various eye conditions, such as uveitis, disorders of the conjunctiva, cornea, vitreous and retina, metabolic or genetic eye diseases or eye tumors, in order to develop better methods of diagnosis and treatment. Patients who require eye surgery to treat an eye disease or other disease in which the eye is involved may participate in this study. Samples of eye tissue and fluid that are normally removed and discarded during eye surgery will instead be given to researchers for study. The tissues will be examined under microscope and studied using sophisticated chemical and biological tests. Immune cells from blood samples may also be examined. These studies will help better understand and diagnose the various eye diseases and to develop more attractive therapies.
Sponsor: NEI
Design: Observational, natural history
Number of patients: Not given
Inclusion/exclusion criteria: All specimens either male or female of any age with ocular disease that are collected at the NEI or its collaborating institutes, will be included in the study. Specimens would consist of material obtained from surgical specimens, biopsy specimens, and from post mortem materials. These would include but would not be limited to cases involving uveal, conjunctival, corneal, vitreoretinal, orbital disorders, tumor and metabolic abnormalities.
Status: This trial is currently recruiting patients.
Information: Contact prpl@mail.cc.nih.gov

Trial: Molecular Genetics of Retinal Degenerations

Purpose: This multinational study will investigate the inheritance of genetic retinal degeneration in families of different nationalities and ethnic backgrounds in order to identify the genes that, when altered, cause retinal degeneration. The findings of this study should help improve diagnosis and methods of treatment for these disorders. Participating institutions include: the National Institutes for Health in Bethesda, Maryland; the University of Miami in Florida; the Casey Eye Institute in Portland, Oregon; the Byrd Health Sciences Center in Morgantown, West Virginia; the University of Texas Southwestern Medical School in Dallas, Texas; the University of Tennessee Health Sciences Center in Memphis; the Prasad Eye Institute in Hyderabad, India; National Center of Excellence in Molecular Biology in Lahore, Pakistan; and the Jules Gonin Hospital in Lausanne, Switzerland. Patients with retinitis pigmentosa and closely related diseases such as Usher syndrome, snowflake vitreoretinal dystrophy and Bietti crystalline dystrophy may be eligible for this study.
Participants undergo the following tests and procedures: Medical and surgical history, including family history of vision problems. Examination to clarify the type of retinal degeneration. Eye examination, including tests of color vision, field of vision and ability to see in the dark Electroretinogram to test the function of visual cells. Hearing tests for patients with a personal or family history of deafness. For middle ear function testing, the patient feels a little air pressure change for a moment and hears some tones. Another test requires the patient to sit quietly with electrodes on the head, forehead and earlobes. Balance testing, including walking in a straight line, standing with eyes closed in the dark and other tests of coordination, and caloric testing. For the caloric testing, any ear wax in the ear canal is removed before the test begins. Then, electrodes are placed on the skin near the eyes and on the forehead. A small amount of cool (sometimes cold) or warm water is instilled into each ear canal, first one and then the other. Blood sample collection for genetic testing.
Sponsor: NEI
Design: Observational, natural history
Number of patients: 200
Inclusion/exclusion criteria: Patients that meet diagnostic criteria for specific retinal degenerations will be recruited from the NEI and collaborating clinics. In addition, this protocol will include patients with other retinal degenerations, including retinitis pigmentosa and Bietti crystalline dystrophy, which have been excluded from the Gyrate atrophy protocol EI 78-001, in which they were formerly included.
Status: This trial is currently recruiting patients.
Information: Contact prpl@mail.cc.nih.gov ■