The Retinal Consultants Update

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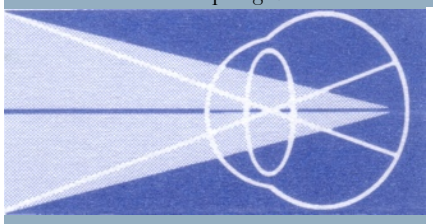

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"All Retina All the Time"

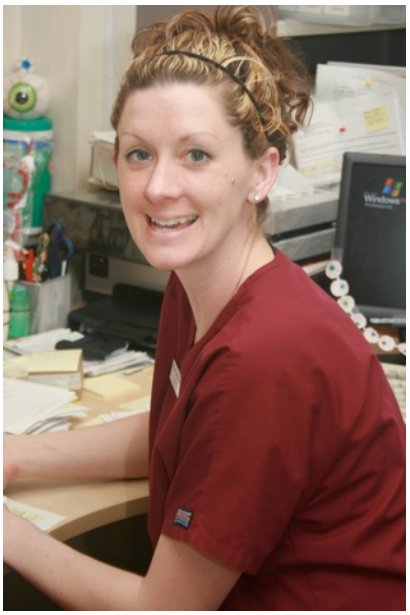
CATT Study Comparing Avastin and Lucentis for Macular Degeneration Releases One Year Results

Retinal Consultants One of 44 Sites in Landmark Study

We again welcome the opportunity to reconnect with our colleagues by keeping you up-to-date on developments in our field and how our practice strives to bring the latest innovations in retinal care to our mutual patients. In this issue, we spotlight our research department, whose continuing mission is to innovate and to provide new treatments through clinical trials. In late April, the much anticipated one year results from the Comparison of AMD Treatments Trials (CATT), were released. Our practice was one of 44 sites in the nation collaborating to make this landmark study a success. In this newsletter we present our perspective and an analysis of what the interim results may mean for the care of macular degeneration.

What Do the Early Results of CATT Mean for the Care of Macular Degeneration?

As you know, we deeply appreciate your referrals for patients with retinal disease. Along with providing what we feel is the highest level of retinal care available, we are integrally involved in clinical trials. These trials help to determine the future of medical care for the posterior segment and give us more and better treatment options. One very important trial, the Comparative AMD Treatment Trial (CATT) just reported significant one year, interim results. We would like to explain these results and how they might in-



Erin McKenna, Lead Clinical Research Coordinator, has been conducting trials and growing the research department since its inception in 2005

fluence drug choice and treatment intervals for your patients.

The CATT started in February 2008 and was designed to compare the relative visual benefit of intraocular Avastin versus Lucentis given monthly or as needed according to a strict protocol. One thousand two hundred and eight patients were ultimately enrolled and randomized to one of four treatment arms and 1185 are included in the analysis. The statistics are excellent and the study design sound. The CATT trial shows that both Avastin and Lucentis give excellent and equivalent visual results at one year. Drug given monthly gave very slightly better results (1 or 2 letters) than "as needed" (prn) dosing, but required 4 to 5 more injections per year. On average patients gained 8 letters of vision with monthly dosing and 6 to 7 with prn dosing. Only 8 percent lost 3 lines or more with treatment and approximately 30% had 15 letter gains. The side effect profiles were also excellent. The rates of death from any cause (1.4%), thromboembolic events (2%), and hypertension were equivalent between the treatment arms. There was a slight increase in the number of hospitalizations for unrelated problems in the Avastin arm that is being investigated further.

From clinical experience over the past 6 years since these remarkable drugs became available, we have learned that some patients respond more favorably to one or the other drug, an effect we have determined empirically. As the CATT trial continues, we have more data on which to base our treatment decisions. Not only will we have 2 year data by the beginning of 2012, but the results of a genetics substudy may give us information on how a given patient might respond to each of the drugs, bringing us one step closer to personalized medicine. Similar trials in Europe and the UK will bolster this data in the next 12 to 18 months.

The full paper is published in the New England Journal of Medicine on May 19, 2011, but became available as an e-publication on April 28 at http://www.nejm.org/doi/pdf/10.1056/NEJMoa1102673.

Retinal Consultants Advance Retinal Care Conducting Clinical Trials

Over the past 6 years our Study Department has grown into a robust clinical trial machine. We offer several different clinical trial options for an assortment of retinal diseases that affect our patients. We currently conduct these trials out of our J Street Sacramento office, our Greenback Lane Sacramento office, and our Chico office location.

You or your patients may wonder, "Why would someone want to participate in a clinical trial?" There are numerous benefits associated with participation. Of course, the outcomes of these trials lead to developments in retinal therapy that benefit us all, but often the most important benefits are the ones that each individual patient experiences.

The perk most frequently cited by study participants is the personal attention they receive. Our research team is devoted to the management of the trials and the care of our study patients. As a result, the study patients routinely come in and work with the same handful of study coordinators. Each patient has someone by his or her side from the time of their diagnosis through each visit. The study coordinators are there to answer questions, provide comfort and communication and make sure their visits are enjoyable. The patients visit schedule depends on the specific trial in which each patient is enrolled, but all study subjects receive extra time and attention that they may not otherwise receive in the clinic.

The study treatments and procedures are often being paid for by a sponsoring pharmaceutical company, and patient transportation to and from study visits is usually reimbursed. Some trials even offer a patient stipend for each visit completed.

The research team here at Retinal Consultants is dedicated to providing the best and latest treatment options for our patients. It is an honor to participate in these important trials to advance our understanding of retinal disease and to bring new treatments to the clinic. Most of all, it is a pleasure to work with the wonderful patients that make this all possible.

Trials

Eligible Patients Sought for Enrollment in Clinical Studies Designed to Assess New Therapies

LUXBIO	This study assesses the safety and efficacy of voclosporin as a therapy for noninfectionous uveitis involving the intermediate and/or posterior segments. Study participants are randomized to an oral calcineurin inhibitor (voclosporin) twice a day or placebo. The study measures the effect of treatment on treating and controlling the uveitis for 3 months.
THROMBOGENICS ADHESION TRIAL	Ocriplasmin is a recombinant human protein, a truncated form of the plasmin protein that has protease activity. Patients with macular degeneration and vitreous traction on the macula may benefit from release of the traction. This is a Phase II trial in which patients receive either a single injection of ocriplasmin or a sham injection, with follow-up visits and continuing care for macular degeneration for 12 months.
UVEITIS (NOVARTIS)	Uveitis is commonly treated with steroid medications, but increasing efforts have been directed at developing non-steroid therapies. This is a Phase II trial studying the effects of AIN457, a monoclonal antibody that binds to the IL-17 receptors which are thought to play an important role in uveitis. This trial is for noninfectious uveitis patients, including intermediate, posterior or pan-uveitis. In this trial patients receive active drug or sham by intravenous infusion or a combination of intravenous infusion and subcutaneous injections.
RACE (Alcon)	Some patients with wet macular degeneration do not respond as robustly as others to standard anti-VEGF injections in the eye. This study tests a novel supplemental injection for patients who have already received between 3 and 12 injections in the past year, but still have evidence of persistent retinal thickening from macular degeneration. Patients are randomized to continued standard treatment with Lucentis or Lucentis with supplemental injections of a novel pharmaceutical agent with potential to achieve further regression of the disease. The trial lasts four months.
SHORE (Genentech)	Intravitreal ranibizumab is a proven effective treatment for macular edema related to retinal vein occlusions. This Phase IV trial is designed to evaluate the efficacy of monthly versus "as needed" dosing of ranibizumab beyond 6 months of treatment. Enrollment includes both branch and central vein occlusion patients.
REGENERON DME - PHASE III (Regeneron)	Avastin and Lucentis are both commonly used in an off-label fashion to treat diabetic macular edema (DME). VEGF Trap-Eye is a new drug with promise that has passed through early safety and efficacy studies and is now being evaluated for its utility in the treatment of diabetic macular edema as well. Patients enrolled in the study will be randomized to treatment with VEGF Trap-Eye treatment at 4 week or 8 week intervals after a loading phase or laser therapy. The trial is three years long.
SANTEN UVEITIS	Currently corticosteroids are the only approved drug class in the United States for noninfectious uveitis. Because of the potential side effects of steroid use, the search continues for alternative therapies. Sirolimus for ocular administration is being tested with a proprietary formulation, for the treatment of noninfectious, posterior uveitis. This study is a 1 year trial assessing the safety and efficacy of intravitreal injections of sirolimus in 3 different dose arms for active, noninfectious uveitis of the posterior segment. Eligible patients must have at least 1+ haze and BCVA of 20/400 or greater in the study eye. The trial consists of a 30 day screening phase, 150 day treatment phase and follow-up visit phase through 1 year. Rescue therapy is available.

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Upcoming Events

Save the Date for RETINA UPDATE 2011

The Retina Update 2011 meeting will be held on Sunday, September 11, 2011, at the Crocker Art Museum from 10 a.m. - 3 p.m. Lunch will be served. At this year's meeting we will again use a format of case based education in vitreo-retinal disease with real-time audience participation. We will also have a presentation by our invited guest speaker, Uday Devgan, MD, FACS, FRCS(Glasg) who will be speaking on "Challenging Cataract Cases."

As always, registration for the meeting is free of charge. Lunch will be provided. Meeting attendees are invited to bring a guest to enjoy complimentary admission to the exhibits at the newly renovated and expanded Crocker Art Museum. Space is limited.

Register online at www.retinaupdate.com

RU2011 Featured Guest Speaker
Uday Devgan, MD,
FACS, FRCS (Glasg)
"Challenging Cataract Cases"

The Retinal Consultants Update Newsletter
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