

Emory Leads National Study Comparing Two Drugs for Macular Degeneration

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Emory Eye Center is the lead center among 47 other eye institutions across the country in a National Eye Institute/National Institutes of Health-funded study to compare two drugs, made by the same company, that treat age-related macular degeneration (AMD).

Daniel F. Martin, MD, Thomas M. Aaberg Sr. Professor of Ophthalmology, and director, Emory Retina Service at Emory Eye Center, will chair the nationwide study.

The Comparison of Age-Related Macular Degeneration Treatments Trials (CATT) began enrolling patients in February 2008. It takes place in 45 sites across the country.

AMD is the leading cause of vision loss in the U.S. for persons over age 60. AMD damages the macula. As the disease progresses, it blurs the patient's central vision. AMD can take two forms, wet and dry. Wet AMD is caused by the abnormal growth of blood vessels under the macula. This leads to rapid loss of central vision. Wet AMD is considered to be advanced AMD and is more severe than the dry form.

Dry AMD, the more common form, occurs when the light-sensitive cells in the macula slowly break down. Untreated dry AMD can progress into wet AMD.

The two drugs, made by Genentech, treat only the "wet" type. Although the FDA approved Lucentis (ranibizumab) in July 2006 for ophthalmic use, its lower-cost "cousin" Avastin (bevacizumab) was used off-label by a number of ophthalmologists before Lucentis was approved. Many physicians continued to use Avastin even after the Lucentis approval. Avastin was approved for colorectal cancer and also is used for lung cancer treatment.

Both Avastin and Lucentis share a similar method of action by inhibiting vascular endothelial growth factor (VEGF), which is the stimulus for abnormal blood vessel growth in "wet" AMD.

Although the two are chemically similar, they are not identical. Additionally, Lucentis' cost is about \$2,000 per dose whereas Avastin's cost is about \$50 per dose.

The FDA approval of Lucentis was based on evidence from clinical trials showing that the drug slows the rate of progression of vision loss from advanced AMD. In addition to a low rate of developing vision loss, approximately one-third of patients treated in these trials had significantly improved vision at 12 months.

"We are excited to begin this study that will compare Lucentis and Avastin head-to-head for the treatment of "wet" AMD" says Dr. Martin. "While it is clear that Avastin is highly effective, we do not know how it compares to Lucentis. Since these are the two primary drugs for the treatment of this disease, it is important for the visual health of the public to understand if there is any difference between them.

"In addition, this study will help refine how these drugs can be used to achieve the best outcome" he says. "It may be that we can inject much less frequently and produce an excellent visual result"

Timothy W. Olsen, MD, director of Emory Eye Center and a retina specialist, says, "The entire community of retinal specialists is anxiously awaiting this important data. This study has huge socio-economic implications, not only for ophthalmic care, but healthcare in general. Newer, so called follow-on biologics may also be studied in a similar manner, and the CATT study will set the stage for future comparisons"

The study, which will enroll about 1,200 patients over a two-year timeframe, will randomly assign study participants with newly diagnosed wet AMD into four groups: Lucentis monthly; Avastin monthly; Lucentis followed by additional injections of Lucentis, as

needed; and Avastin followed by additional injections of Avastin, as needed. The trial should conclude sometime in 2010.

At Emory, recruitment has just begun for those individuals with newly diagnosed "wet" type age-related macular degeneration in an eye that has not been treated. Please call 404-778-7777 for more information.