

AMD TREATMENTS

Nutritional Supplement Reduces Risk of Advanced AMD

The Age-Related Eye Disease Study (AREDS) — a landmark investigation conducted by the National Eye Institute (NEI) — determined that antioxidant supplementation can slow the progression of AMD. The AREDS formulation is an over-the-counter antioxidant supplement recommended for people who are at risk of developing advanced forms of either dry or wet AMD. The formulation includes the antioxidants beta carotene, vitamin E, and vitamin C, as well as the nutrients zinc and copper.

The NEI recently completed a second AREDS study (AREDS2) to evaluate the potential benefits of the antioxidants lutein and zeaxanthin and the omega-3 fatty acids docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA).

The results of AREDS2 showed that DHA and EPA did not confer additional benefit in reducing AMD risk. The researchers from AREDS2 did recommend that beta carotene in the original formula be replaced with lutein, because beta carotene can increase lung cancer risk in current and former smokers. For more information on the AREDS2 study, visit www.areds2.org.

Lucentis™ Preserves Vision in People with Wet AMD

Developed by Genentech, Lucentis is effective in reducing the risk of losing vision from the abnormal blood vessel growth under the retina associated with wet AMD. The drug has been available since 2006. A two-year study showed that 95 percent of people with wet AMD who received monthly injections of Lucentis experienced no significant loss in visual acuity. Genentech also reported moderate visual improvement in 24.8 percent of participants treated

with a 0.3 mg dose of Lucentis and 33.8 percent of participants treated with a 0.5 mg dose.

Genentech is reporting progress in the development of a device aimed at reducing the number of Lucentis injections required to inhibit wet AMD. The company's 20-participant Phase Ia clinical trial of a sustained delivery device, known as a port delivery system (PDS), is showing positive results for safety and the diffusion of Lucentis to affected areas of the retina. Investigators believe that the PDS can provide four months of therapy before needing to be refilled.

Avastin® used Off-Label to Treat Wet AMD

A colorectal-cancer drug called Avastin® — a drug similar to Lucentis — has been used “off-label” by some ophthalmologists to treat wet AMD. The National Eye Institute conducted a clinical study of Avastin for the treatment of wet AMD to better determine the drug's long-term safety and effectiveness. In the study, Avastin

was compared to Lucentis. The two-year study showed that the drugs were similar in safety and efficacy.

EYLEA™ Preserves Vision in Wet AMD with Fewer Injections

Regeneron's wet AMD treatment, Eylea (also known as VEGF Trap), blocks the development of unhealthy blood vessels that lead to vision loss. Regeneron reports that in clinical trials, Eylea treated wet AMD as effectively as Lucentis, but with fewer eye injections. Genentech, maker of Lucentis, recommends monthly injections of their treatment. Regeneron, maker of Eylea, reports that their therapy can be injected every eight weeks after monthly dosing for the first 12 weeks of treatment. Eylea was approved by the FDA in November 2011.

Implantable Miniature Telescope Improves Central Vision

The FDA has approved the use of an implantable miniature telescope (IMT) for enhancing the central vision of people with end-stage, untreatable age-related

macular degeneration (AMD). The IMT provides improved central and detailed vision by focusing and magnifying images onto the functional, outer regions of the recipient's retina. People with advanced AMD usually experience degeneration of the macula or central region of the retina. The IMT was developed by VisionCare Ophthalmic Technologies.

EMERGING AMD TREATMENTS CURRENTLY IN CLINICAL TRIALS

RetinoStat® — Oxford BioMedica, a gene therapy company in the United Kingdom, is conducting a Phase I clinical trial of its gene therapy for the treatment of wet AMD. Known as RetinoStat, the treatment works by blocking the growth of leaky, unhealthy blood vessels under the retina that cause vision loss in wet AMD. The study is taking place at the Wilmer Eye Institute at Johns Hopkins. Earlier research funded by FFB made this trial possible. Early study results indicate the therapy is blocking the growth of vision-robbing blood vessels.

Advanced Cell Technology

(ACT) — The biopharmaceutical company ACT has launched a Phase I/II clinical trial of its cell-based therapy for people with dry AMD. The study is taking place at multiple sites in the U.S. Participants in the study are receiving transplants of retinal pigment epithelial cells derived from stem cells. The company believes the treatment may slow the progress of the disease, saving and potentially restoring vision. Early results of the treatment have been encouraging. The Foundation funded earlier lab studies of this treatment approach, which made ACT's clinical trial possible.

StemCells, Inc. — The biopharmaceutical company StemCells, Inc. has launched a Phase I/II clinical trial of its neural stem cell therapy for people with dry AMD. The transplanted stem cells are designed to release survival factors to keep the retina's existing cells healthy. The study is taking place at the Retina Foundation of the Southwest in Dallas. Early results show that the

treatment is slowing the macular degeneration.

ACUCELA — The biopharmaceutical company Acucela is conducting a three-year, Phase IIb/III clinical trial in the U.S. of ACU-4429, an orally administered visual cycle modulator, for the treatment of dry age-related macular degeneration (AMD). By slowing the visual cycle, the drug is intended to reduce the build-up of toxic by-products in the retina (retinal pigment epithelium) that cause vision loss in dry AMD and potentially other retinal conditions. The drug has shown promising results in a preclinical study and a Phase I clinical trial.

The Foundation Funds Pivotal Genetic Research for AMD

In early 2005, FFB-funded researchers identified variations in a gene known as Complement

Factor H (CFH), which are implicated in as many as 50 percent of all cases of AMD. In early 2006, these same investigators found that variations in CFH along with variations in two other newly identified genes, factor B (BF) and complement component (C2), are present in 74 percent of AMD cases.

Though the environmental and genetic causes of AMD are complex, these landmark findings confirm a genetic influence in developing AMD. And, these genes give a clear target for the development of future, more effective therapies. The CFH finding strongly suggests that the immune system and related inflammatory responses are key factors in developing AMD. Future therapies are being directed toward stopping the effects of CFH variations and other related genes.

The Foundation publishes frequent updates on the latest advancements in research and clinical trials for AMD and similar diseases.

www.FightBlindness.org