Age-Related Eye Disease Study (AREDS) (NEI Clinical Studies)

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Press Release Announcing Results

Summary of AREDS Results

Age-Related Eye Disease Study (AREDS)

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Purpose
- To assess the clinical course, prognosis, and risk factors of age-related macular degeneration (AMD) and cataract.
- To evaluate, in randomized clinical trials, the effects of pharmacologic doses of (1) antioxidants and zinc on the progression of AMD and (2) antioxidants on the development and progression of lens opacities.

Background
AMD and cataract are the leading causes of visual impairment and blindness in the United States. Based on many clinical studies, it is apparent that the frequency of both diseases increases dramatically after age 60. Although excellent treatments for cataract are available, there are no equivalent treatments for AMD. As the average lifespan of our population increases, the number of people who develop AMD will increase dramatically in the years ahead. Unless successful means of prevention or treatment are developed, blindness from AMD -- and its importance as a public health problem -- will increase.

Neither the etiology nor the natural history of AMD or cataract is known. Epidemiologic studies suggest that a number of risk factors may be associated with AMD and cataract, but the strength of the evidence in support of these hypotheses varies. Possibly
associated with AMD are personal characteristics, such as age, race, height, family history, and strength of hand grip; ocular characteristics, such as hyperopia and color of iris; and cardiovascular diseases, smoking, lung infections, and chemical exposures. Clinical and laboratory studies suggest the following factors may be associated with progression of AMD: drusen type, choroidal vascular diseases, and photic injury.

Epidemiologic studies of cataract suggest that associated risk factors may include personal characteristics, such as age, sex, race, occupation, and educational status; ocular characteristics, such as iris color; and diabetes mellitus, hypertension, drug exposure, smoking, and sunlight exposure. Animal studies and observational epidemiologic studies suggest that deficiencies in vitamins C and E, carotenoids, and the trace elements zinc and selenium also may be associated with the development of the two diseases, especially cataract. Although surgical treatment to remove cataract is very effective, cataract surgery carries risks, as does any other surgery. Therefore, many research efforts focus on preventing or slowing cataract development, as well as on determining the causes of cataract formation.

Description
The Age-Related Eye Disease Study (AREDS) is a major research program to improve our understanding of the predisposing factors, clinical course, and prognostic factors of AMD and cataract. Eligible patients are randomized to treatment with placebo, antioxidants, zinc, or antioxidants plus zinc, and are followed for a minimum of 5 years.

Patient Eligibility
Men and women between the ages of 55 and 80 years whose macular status ranges from no evidence of AMD in either eye to relatively severe disease with vision loss in one eye but good vision in the fellow eye (20/30 or better) are eligible for the study provided that their ocular media are clear enough to allow good fundus photography.

Patient Recruitment Status
Completed. Patient recruitment began in September 1990. The first participant was enrolled November 1992, and recruitment ended in July 1995 for all but minority participants. The last participant was enrolled January 1998. A total of 4,757 participants were enrolled.
Current Status of Study
Ongoing.

Results
AREDS researchers found that people at high risk of developing advanced stages of AMD lowered their risk by about 25 percent when treated with a high-dose combination of vitamin C, vitamin E, beta-carotene, and zinc. In the same high risk group -- which includes people with intermediate AMD, or advanced AMD in one eye but not the other eye -- the nutrients reduced the risk of vision loss caused by advanced AMD by about 19 percent. For those study participants who had either no AMD or early AMD, the supplements did not provide an apparent benefit.

In the cataract portion of the study, researchers discovered that the same nutrients had no significant effect on the development or progression of age-related cataract.

Publications


The Age-Related Eye Disease Research Group: Risk factors associated with age-related nuclear and cortical cataract. A case-control study in the Age-Related Eye Disease Study.


Gensler GR, Lindblad AS, Age-Related Eye Disease Study (AREDS) Research Group: Evaluation of a two-phase enrollment design: Experience of the Age-Related Eye Disease Study. Abstract, 2nd Joint Meeting, Society for Clinical Trials and International Society
for Clinical Biostatistics, Boston, Massachusetts, July 6-10, 1997.


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