

Age-Related Eye Disease Study 2 (AREDS2) – 2012



Objective

To evaluate the safety and efficacy of substituting lutein and zeaxanthin (L+Z) for beta-carotene, adding omega-3 long-chain polyunsaturated fatty acids (LCPUFAs), and reducing zinc in AREDS vitamins formulations for decreasing the risk of AMD progression.

Methods

Design: Multicenter RCT

Sample Size: N = 4023

Treatment Groups:

- AREDS only (placebo): 1012
- AREDS + L+Z: 1044
- AREDS + Omega-3s: 1069
- AREDS + L+Z + Omega-3s: 1078
- Secondary randomization to:
control, no beta-carotene, low zinc,
or low-zinc & no beta-carotene

Outcome Measures:

- Disease progression to advanced AMD
- Measured by annual fundus photographs

Results

Point 1: No statistically significant reduction in disease progression was found in the groups assigned to take L+Z and/or omega-3 LCPUFAs in addition to the AREDS supplement

- Omega-3 LCPUFAs HR 0.98 (95% CI 0.89-1.08)
- Lutein+Zeaxantin HR 0.91 (0.82-1.00), P = 0.05

Point 2: No statistically significant reduction in disease progression was found with differing doses or zinc or with omission of beta-carotene

- Low-zinc HR 1.06 (95% CI 0.95-1.19)
- No beta-carotene HR 1.07 (0.94-1.20)

Point 3: Significantly more cases of lung cancer occurred in patients who had history of smoking cigarettes and were taking beta-carotene (2%) versus those not taking beta carotene (0.9%), P=0.04

- Substituting L+Z for beta-carotene is appropriate for AMD protection

TLDR: AREDS2 vitamins should substitute Lutein and Zeaxanthin for beta-carotene; continue with Zinc, Copper, Vit C and E.

AREDS2 Research Group; Chew EY, Clemons T, SanGiovanni JP, Danis R, Domalpally A, McBee W, Sperduto R, Ferris FL. The Age-Related Eye Disease Study 2 (AREDS2): study design and baseline characteristics (AREDS2 report number 1). *Ophthalmology*. 2012 Nov;119(11):2282-9. doi: 10.1016/j.ophtha.2012.05.027. Epub 2012 Jul 26. PMID: 22840421; PMCID: PMC3485447.

The Age-Related Eye Disease Study 2 (AREDS2) Research Group*. Lutein + Zeaxanthin and Omega-3 Fatty Acids for Age-Related Macular Degeneration: The Age-Related Eye Disease Study 2 (AREDS2) Randomized Clinical Trial. *JAMA*. 2013;309(19):2005–2015. doi:10.1001/jama.2013.4997