

## Resources-Doctor-AMD-AREDS2

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| <b>Study Title:</b><br>Lutein + Zeaxanthin and Omega-3 Fatty Acids for Age-Related Macular Degeneration  |
| <b>Study Author(s):</b> National Eye Institute/National Institute of Health, Lead Investigator: Dr. Emily Chew   |
| <b>Journal:</b> Journal of American Medical Association May 15, 2013 – Vol 309, No. 19   |
| <b>Sponsor:</b> NEI/NIH, Study Meds were provided by Alcon, Bausch & Lomb, DSM and Pfizer  |
| <b>Study Objective:</b> <ol style="list-style-type: none"><li>1. To determine whether adding lutein + Zeaxanthin decreases the risk of developing advanced AMD</li><li>2. To determine whether DHA + EPA decreases the risk of developing advanced AMD</li><li>3. To determine whether Lutein + Zeaxanthin + EPA + DHA decreases the risk of developing advanced AMD</li><li>4. Evaluate the effect of eliminating beta carotene from the AREDS formulation</li><li>5. Evaluate the effect of lowering zinc doses in the AREDS formulation</li></ol> <ul style="list-style-type: none"><li>• <b>Design and Participants:</b><br/>Multi-center, randomized, double-masked, placebo-controlled phase 3 study<br/>4203 participants aged 50 to 85 years at risk for progression to advanced AMD with bilateral large drusen or large drusen in 1 eye and advanced AMD in the fellow eye</li><li>• <b>Study Design:</b> Participants were randomized to receive:<ol style="list-style-type: none"><li>1. Lutein (10mg) + Zeaxanthin (2mg)</li><li>2. DHA (350mg) + EPA (650mg)</li><li>3. Lutein + Zeaxanthin + EPA + DHA</li><li>4. Placebo</li></ol>All Participants took one of the following:<ol style="list-style-type: none"><li>1. Original AREDS formulation</li><li>2. Original AREDS formulation eliminating Beta-Carotene</li><li>3. Original AREDS formula with lowered zinc 25mg</li><li>4. Original AREDS formula without Beta-Carotene and lowered zinc</li></ol></li></ul> |
| <b>Primary Outcome:</b><br>Development of advanced AMD. The unit of analyses used was by eye.  |
| <b>Results:</b><br><b>Median follow-up was 5 years with 1940 study eyes.</b> <ul style="list-style-type: none"><li>• 31% Progression to advanced AMD for placebo</li><li>• 29% progression to advanced AMD for Lutein + Zeaxanthin</li><li>• 31% progression to advanced AMD for DHA+EPA</li><li>• 30% progression to advanced AMD for Lutein + Zeaxanthin + DHA+EPA</li><li>• Null effect of beta carotene elimination or lower-dose zinc on progression to advanced AMD.</li></ul>   |

### Conclusions:

- Addition of lutein + zeaxanthin, DHA+EPA, or both to the AREDS formulation in primary analyses did not further reduce the risk of progression to advanced AMD.
- Given that more lung cancers were noted in the beta carotene vs no beta carotene group, Lutein + Zeaxanthin could be an appropriate carotenoid substitute in AREDS formulation.

## NutriU Analysis

### Study Objective:

- This study did not include early stage or prevention of onset of AMD

### Study Design:

- Study used “inadequate dose”, “inadequate duration of treatment” or both  
**(None of the participants reached 8% RBC saturation)**
- The form of Omega-3 LCPUFA was an Ethyl Ester
- DHA:EPA ration may be inappropriate

### Primary Outcome:

#### Advanced AMD showed - Favors Treatment

- Lutein + Zeaxanthin
- AREDS supplementation with Lutein + Zexanthin with **no beta carotene**

#### Neovascular AMD showed - Favors Treatment

- Lutein + Zeaxanthin
- AREDS supplementation with Lutein + Zexanthin with **no beta carotene**

#### Central Geographic Atrophy showed – Favors Treatment

- Lutein + Zeaxanthin
- AREDS supplementation with Lutein + Zexanthin with **no beta carotene**

### Discussion notes from study:

This study did not address primary prevention.

Observational studies suggest that higher dietary intake of lutein+zeaxanthin, omega-3 LCPUFA DHA/EPA or both are associated with a decreased risk of DEVELOPING advanced AMD.

The researchers suggest that earlier stages of AMD are more responsive to treatment with EPA+DHA.