

CARMA STUDY ABSTRACT

Carotenoids and co-antioxidants in age-related maculopathy: design and methods.

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Age-related macular degeneration (AMD), is the leading cause of blind registration in the Western World among individuals 65 years or older. Early AMD, a clinical state without overt functional loss, is said to be present clinically when yellowish deposits known as drusen and/or alterations of fundus pigmentation are seen in the macular retina. Although the etiopathogenesis of AMD remains uncertain, there is a growing body of evidence in support of the view that cumulative oxidative damage plays a causal role. Appropriate dietary antioxidant supplementation is likely to be beneficial in maintaining visual function in patients with AMD, and preventing or delaying the progression of early AMD to late AMD. The Carotenoids in Age-Related Maculopathy (CARMA) Study is a randomized and double-masked clinical trial of antioxidant supplementation versus placebo in 433 participants with either early AMD features of sufficient severity in at least one eye or any level of AMD in one eye with late AMD (neovascular AMD or central geographic atrophy) in the fellow eye. The aim of the CARMA Study is to investigate whether lutein and zeaxanthin, in combination with co-antioxidants (vitamin C, E, and zinc), has a beneficial effect on visual function and/or prevention of progression from early to late stages of disease. The primary outcome is improved or preserved distance visual acuity at 12 months. Secondary outcomes include improved or preserved interferometric acuity, contrast sensitivity, shape discrimination ability, and change in AMD severity as monitored by fundus photography. This article outlines the CARMA Study design and methodology, including its rationale.