

## Clinical Trial of Lutein in Patients With Retinitis Pigmentosa Receiving Vitamin A

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### ABSTRACT

**Objective** To determine whether lutein supplementation will slow visual function decline in patients with **retinitis** pigmentosa receiving vitamin A.

**Design** Randomized, controlled, double-masked trial of 225 nonsmoking patients, aged 18 to 60 years, evaluated over a 4-year interval. Patients received 12 mg of lutein or a control tablet daily. All were given 15 000 IU/d of vitamin A palmitate. Randomization took into account genetic type and baseline serum lutein level.

**Main Outcome Measures** The primary outcome was the total point score for the Humphrey Field Analyzer (HFA) 30-2 program; prespecified secondary outcomes were the total point scores for the 60-4 program and for the 30-2 and 60-4 programs combined, 30-Hz electroretinogram amplitude, and Early Treatment Diabetic Retinopathy Study acuity.

**Results** No significant difference in rate of decline was found between the lutein plus vitamin A and control plus vitamin A groups over a 4-year interval for the HFA 30-2 program. For the HFA 60-4 program, a decrease in mean rate of sensitivity loss was observed in the lutein plus vitamin A group ( $P = .05$ ). Mean decline with the 60-4 program was slower among those with the highest serum lutein level or with the highest increase in macular pigment optical density at follow-up ( $P = .01$  and  $P = .006$ , respectively). Those with the highest increase in macular pigment optical density also had the slowest decline in HFA 30-2 and 60-4 combined field sensitivity ( $P = .005$ ). No significant toxic effects of lutein supplementation were observed.

**Conclusion** Lutein supplementation of 12 mg/d slowed loss of midperipheral visual field on average among nonsmoking adults with **retinitis** pigmentosa taking vitamin A.

**Application to Clinical Practice** Data are presented that support use of 12 mg/d of lutein to slow visual field loss among nonsmoking adults with **retinitis** pigmentosa taking vitamin A.

**Trial Registration** ClinicalTrials.gov Identifier: [NCT00346333](https://clinicaltrials.gov/ct2/show/study/NCT00346333)