

Eye drops slow nearsightedness progression in kids, study finds

June 1 2023, by Emily Caldwell



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The results of a new clinical trial suggest that the first drug therapy to slow the progression of nearsightedness in kids could be on the horizon.



The three-year study found that a daily drop in each eye of a low dose of atropine, a drug used to dilate pupils, was better than a placebo at limiting eyeglass prescription changes and inhibiting elongation of the eye in nearsighted children aged 6 to 10.

That elongation leads to <u>myopia</u>, or <u>nearsightedness</u>, which starts in young kids and continues to get worse into the <u>teen years</u> before leveling off in most people. In addition to requiring life-long vision correction, nearsightedness increases the risk for <u>retinal detachment</u>, <u>macular degeneration</u>, cataracts and glaucoma later in life—and most corrective lenses don't do anything to stop myopia progression.

"The idea of keeping eyeballs smaller isn't just so people's glasses are thinner—it would also be so that in their 70s they don't suffer <u>visual impairment</u>," said lead study author Karla Zadnik, professor and dean of the College of Optometry at The Ohio State University.

"This is exciting work for the myopia research community, which I've been part of for 35 years. We've talked about treatment and control for decades," she said. "And it's exciting to think that there could be options in the future for millions of children we know are going to be myopic."

The results of the CHAMP (Childhood Atropine for Myopia Progression) trial are published today (June 1, 2023) in *JAMA Ophthalmology*.

About one in three adults worldwide is nearsighted, and the global prevalence of myopia is predicted to increase to 50% by 2050. Though one federally approved contact lens can slow progression of nearsightedness, no <u>pharmaceutical products</u> are approved in the United States or Europe to treat myopia.

Animal studies years ago hinted at atropine's ability to slow the growth



of the eye, but the full-strength drug's interference with near vision and concerns about pupil dilation hindered early considerations of its potential as a human therapy for myopia. More recent research has suggested a low dose of atropine might be the ticket.

This new double-masked, randomized phase 3 trial assessed the safety and effectiveness of two low-dose solutions, with atropine concentrations of either .01% or .02%, versus placebo. Treatment for each of the 489 children aged 6 to 10 assessed for the drug's effectiveness consisted of one daily drop per eye at bedtime, which minimized the disruption of any blurring effects atropine might have on vision.

Researchers were a bit surprised to find that the most significant improvements at all time points compared to placebo resulted from the solution containing .01% of atropine. Though the .02% atropine formulation was also better at slowing progression of myopia than placebo, the results were less consistent.

"The .01% story is clearer and more obvious in terms of significantly slowing both the growth of the eye as well as then resulting in a lower glasses prescription," Zadnik said.

Including a measure of the eye's growth was a key component of the study because "the field is actually moving toward axial elongation being as important as or more important than the glasses prescription in terms of the most meaningful outcome," she said. "If we're trying to slow eye growth to prevent bad outcomes for people in their 80s, measuring the eye growth directly is really important."

The drugs' safety was assessed in a larger sample of 573 participants that also included children as young as 3 and up to age 16. Both low-dose formulations were safe and well tolerated. The most common side



effects were sensitivity to light, allergic conjunctivitis, eye irritation, dilated pupils and blurred vision, although reports of these side effects were few.

The CHAMP trial was the first study of low-dose atropine to include placebo controls for three years and to involve a large, diverse population recruited from 26 clinical sites in North America and five countries in Europe. In a second section of the trial, researchers are evaluating how the eyes respond when the treatment is over.

The experimental drug is made without preservatives, and if federally approved as a therapy, would be distributed in single-use packaging for convenience and to prevent contamination. Off-label low-dose atropine that can currently be obtained at compounding pharmacies may contain preservatives that can lead to dry eye and corneal irritation, researchers noted.

More information: Karla Zadnik et al, Efficacy and Safety of 0.01% and 0.02% Atropine for the Treatment of Pediatric Myopia Progression Over 3 Years, *JAMA Ophthalmology* (2023). DOI: 10.1001/jamaophthalmol.2023.2097

Provided by The Ohio State University

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