INPLASY PROTOCOL

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None declared.

Efficacy and safety of 0.01% atropine in childhood myopia: A meta-analysis

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Review question / Objective: **Is 0.01% atropine an effective and safe treatment for childhood myopia?**
Condition being studied: **Myopia is a worldwide public health concern with a significant socioeconomic burden. Its growing prevalence has sharply increased in many East Asian communities, affecting 80% to 90% of young adults. A recent review predicted that 49.7% of the world's population will be myopic by 2050, and 9.8% will be high myopia cases. Furthermore, the global economic cost of vision impairment, which is predominantly due to myopia, could reach more than US$200 billion annually. Notably, high myopia is associated with excessive eyeball growth, leading to severe sight-threatening complications, such as retinal detachment and glaucoma. Therefore, finding an effective and safe treatment to slow down myopia progression is urgently needed.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 April 2021 and was last updated on 16 April 2021 (registration number INPLASY202140082).

INTRODUCTION

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METHODS

Participant or population: the participants with a diagnosis of myopia were younger than 18 years.

Intervention: 0.01% atropine.

Comparator: Placebo.

Study designs to be included: Randomized control trials (RCTs), cohort studies, or case-control studies.

Eligibility criteria: Studies were included in the systematic review if (1) they were randomized control trials (RCTs), cohort studies, or case-control studies; (2) they compared a group treated with 0.01% atropine for myopia control with a control group; (3) the participants with a diagnosis of myopia were younger than 18 years; (4) at least one efficacy or safety outcome relevant to our review was reported in the studies, including the change in SER, AL, accommodative amplitude, and pupil size; and (5) the mean follow-up period was at least one year. We excluded review articles, case reports, case series, animal or laboratory studies, and conference abstracts.

Information sources: Studies describing the efficacy of 0.01% atropine in myopia control before March 2021 were identified from the PubMed, Embase, and Cochrane Library databases. No language restrictions were applied. The keywords "0.01% atropine", "myopia control", and their synonyms and derivatives were used. Details of the search strategies are described in eTable 2. The "related articles" option in PubMed was used to broaden the search results, and all abstracts, studies, and citations retrieved were reviewed. Furthermore, we assessed the reference sections of the retrieved articles to identify other relevant studies. Lastly, unpublished studies were retrieved from the ClinicalTrials.gov registry (https://clinicaltrials.gov/), the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT, https://eudract.ema.europa.eu/), and the International Clinical Trials Registry Platform (ICTRP, https://www.who.int/ictrp/en/).

Main outcome(s): The efficacy outcomes were the changes in SER and AL per year. The safety outcomes included changes in accommodative amplitude, photopic pupil size, and mesopic pupil size.

Quality assessment / Risk of bias analysis: The methodological quality of the non-randomized studies was assessed using Risk Of Bias In Non-randomized Studies - of Interventions (ROBINS-I), and that of RCTs was evaluated using the Cochrane Collaboration's Risk of Bias Assessment tool (RoB v.2.0). Decisions recorded individually by two reviewers were compared, and disagreements were resolved by a third reviewer.

Strategy of data synthesis: The effect size of each study was presented as weighted mean difference (WMD) with 95% confidence intervals (CIs) for continuous outcome measures (SER, AL, accommodative amplitude, mesopic pupil size, and photopic pupil size). The pooled estimates and their CIs was calculated using the DerSimonian and Laird random-effects model considering the heterogeneity of the study populations.

Subgroup analysis: We conducted a subgroup analysis according to the study design, study population, mean age, mean baseline refraction, and associated characteristics to explore the potential heterogeneity.

Sensitivity analysis: The Modified Hartung–Knapp/Sidik–Jonkman (HKSJ) adjustment was employed to adjust type I errors and avoid inaccurate CIs as sensitivity analysis

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if the included study number of each outcome was less than ten and the pooled effect was statistically significant. In addition, we performed a leave-one-out sensitivity analysis to evaluate the influence of each study on the overall effect by removing studies sequentially.

Country(ies) involved: Taiwan.

Keywords: 0.01% atropine, myopia control.

Contributions of each author:

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