

STudy of Atropine to Reduce (STAR) Myopia Progression in Children: 24-Month Results of a Randomized, Double-Masked, Vehicle-Controlled Trial of Atropine Sulfate 0.01% and 0.03%

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SUPPLEMENTAL INFORMATION

Measurement of annual myopia progression

Annual myopic progression rate was defined as the negative change in SE (averaged over both eyes) from baseline, divided by the number of days since baseline, multiplied by 365.25.

Information on the pH and pD of the product

Atropine sulfate 0.01% and 0.03% solutions are a clear, colorless liquid with a pH of 5.4 and an osmolality of 280 mOsm/kg. Each formulation contains BAK 0.1 mg/mL (0.01%) as a preservative; other excipients are citric acid, sodium citrate, sodium chloride, and sodium hydroxide/hydrochloric acid for pH adjustment, with D₂O as a solvent/excipient.

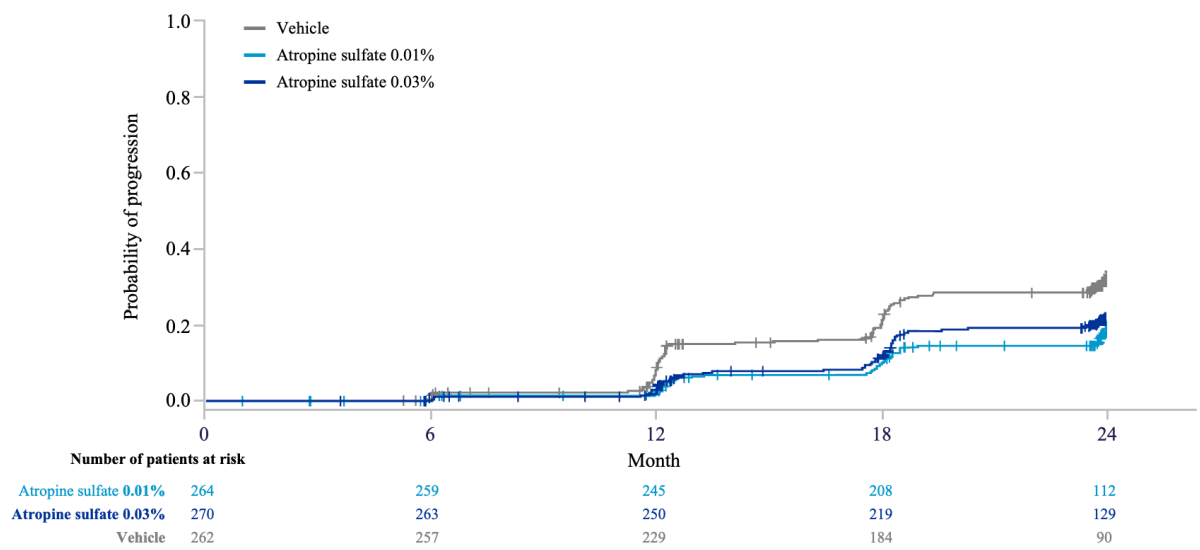
D₂O is included as a stabilizing excipient. When compared to purified H₂O, the use of D₂O was accepted by regulators on pharmaceutical-quality grounds based on improved chemical stability of the atropine solution. For acidity measurements in deuterated media, the below conventional relation applies:

$$\text{pD} = \text{pH (meter reading)} + 0.4$$

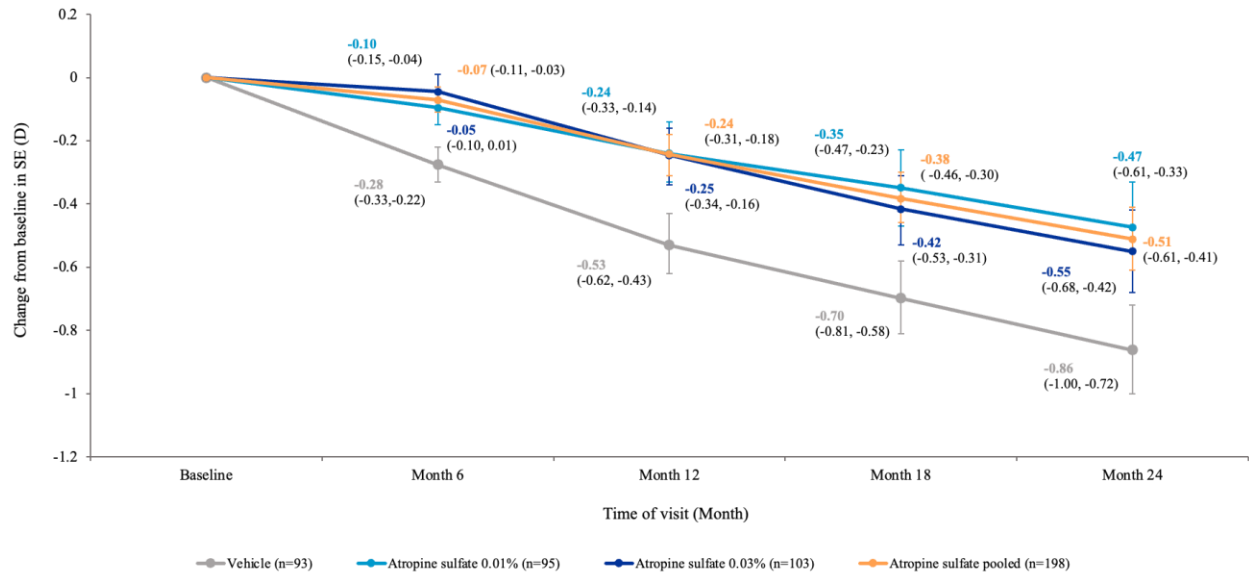
Therefore, a standard water-calibrated pH electrode reads approximately 0.4 units lower than the corresponding pD value in D₂O-containing solutions (specialized convention for deuterated solutions). The pH reported above (5.4) reflects the regulatory meter-based reading for the finished product.

In the STAR study, the vehicle matched the excipients of the active formulations but used H₂O in place of D₂O; all three masked solutions (vehicle, atropine sulfate 0.01%, and atropine sulfate 0.03%) contained BAK as preservative.

Supplementary Fig. 1 Kaplan–Meier estimates. Time to myopia progression of -0.75 D/year or worse through month 24 – full analysis set.



Supplementary Fig. 2 Mean change from baseline in SE through month 24 in patients with progression rate of -0.5 D/year or worse (Fast Progressor Subgroup 1). Graph depicts mean change from baseline in SE at each time point (95% confidence interval).



D diopters, *SE* spherical equivalent.

Supplementary Table 1. List of sites and principal investigators in the STAR study.

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