

0.05% atropine for myopia treatment for children in Estonia:

Development of a protocol to prepare eye drops and the effect and tolerability in a twelve-month treatment in East Tallinn Central Hospital

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BACKGROUND AND IMPORTANCE

According to a 2023 study, about 22% of 5th grade students are nearsighted. 22% of 10-14 year olds are also nearsighted

- 17,508 children with myopia could potentially require atropine treatment
- **Myopia increases the risk of serious eye diseases** (MMD, RD, glaucoma, and cataracts)
- Atropine therapy is an **off-label drug** to slow the progression of myopia in minor children
- There are more studies on atropine in patients of Asian origin. The effect in Europe is **still being determined**
- According to LAMP study (1), 0,05% atropine has the best result and less side effects
- There is **no medication treatment available in Estonia**. Myopia can be corrected with glasses and contact lenses, and refractive surgery which is **only possible in adulthood**
- There are not enough studies/results to start producing atropine drops at a national level



MATERIALS AND METHODS

A 12-month 0,05% atropine eye drop study on 34 myopic patients was conducted (visits at baseline, one week, 1, 3, 6, 9, 12 months after treatment initiation).

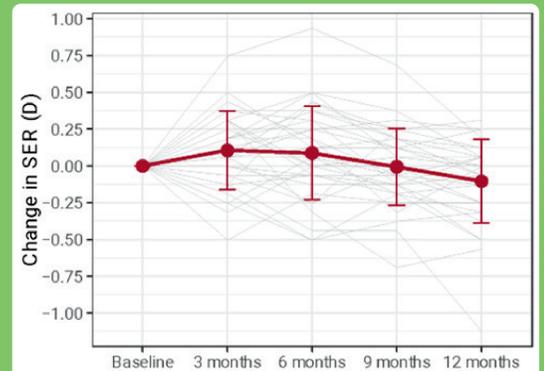
- Patients (16 boys and 18 girls) with a median age of 11.8 years (4-16 years) with a median SER -5.0 D were treated.
- Cycloplegic refraction was measured at baseline and on 3, 6, 9, and 12 months. The mean values of the right and left eyes were calculated and used for analysis
- Side effects were reported at every visit
- Hospital pharmacy prepared 7 unit-dose 0,05% atropine eye drops in class A cleanroom conditions weekly.

AIM AND OBJECTIVES

1. Develop a protocol to prepare 0,05% atropine drops in class A cleanroom by the hospital pharmacy that would be **the first medication treatment** option in Estonia at the moment
2. Develop a unit-dose eye drop that would be affordable for the patients
3. Analyse the effect and **tolerability of 0,05% atropine eye drops** on Estonian children
4. To obtain **health insurance funding** for the drug
5. To increase co-operation between hospital pharmacies to enable such treatment all over Estonia

RESULTS AND IMPACT

- A protocol to prepare 0,05% atropine unit-dose eye drops for 7 days was implemented.
- **From baseline to 12 months, mean change in SER was -0.10 D**



- ✓ Since January 2025 – treatment is reimbursed by **Health Insurance Fund**. The number of patients prescribed atropine treatment has increased by at least **26,6%** each year.
- ✓ Since June 2025- atropine eye drops are also prepared by **Pärnu Hospital Pharmacy**. They are currently treating 3 patients.

- ✓ After 2 years, treatment was discontinued with **one patient** who had no progression and therefore treatment was no longer indicated.
- ✓ The majority of patients have continued treatment because they see an **excellent effect** from it.



WHAT'S NEXT?

Thorough and successful stability studies:



Shelf life of the medicine is more than 1 week



The medicine is prepared only once a week



More atropine drops are prepared in less time



More patients from all over Estonia



0,05% Atropine is also available in other hospitals.



Hopefully, atropine eye drops will be produced in Europe that are **accessible to everyone**.

REFERENCES

1 Yam JC, Li FF, Zhang X, Tang SM, Yip BHK, Kam KW, et al. Two-Year Clinical Trial of the Low-Concentration Atropine for Myopia Progression (LAMP) Study: Phase 2 Report. Ophthalmology. 2020 Jul;127(7):910-9



ACKNOWLEDGMENTS

Dr. Teele Palumaa (ophthalmologist) and Dr. Delis Linntam (ophthalmologist)
 Jekaterina Mik (pharmacist), Natalja Prokofjeva (pharmacy technician) and Marju Friedenthal (assistant)
 Kerttu Michelson (ophthalmology nurse) and Terje Peetersoo (Head nurse of ophthalmology Clinic)

