

Title of project:

Tropical application of low-concentration (0.01%) atropine on the human eye with fast and slow myopia progression rate

Summary

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Myopia (short-sightedness) has been an epidemic worldwide. In Hong Kong, the prevalence of myopia is approximately 80% at the end of childhood, and the rate of myopia progression among children varies. **Tropical application of 0.01% atropine is a newly recommended pharmacological myopia control treatment.** Recent studies reported that it is effective to slow down myopia progression. **The findings from my GRF 2013 study showed that young children with an initial weakened central electrical signal from the inner retina had faster myopia progression. This indicates that the central retinal electro-activity is an important indicator to find out the predisposed risk of fast myopia progression.** Since the electro-retinal activities measured by my new protocol can classify the children into fast or slow myopia progression group, we speculate that studying the effect of atropine on these two groups will help us better understand the effectiveness of the drug in myopia control for the children with different predisposed risks.

There has been no study investigating the treatment effect of atropine on the children with either fast or slow myopia progression rate, neither has there been clinical finding to demonstrate whether the children with either fast or slow myopia progression will show the same treatment effect of atropine. Hence, longitudinally studying the underlying retinal activities that regulate the control of myopia progression using atropine in these two group of children will help evaluate the clinical effectiveness and improve the clinical judgement in prescribing this treatment.

Our project is a **24-month longitudinal randomized controlled trial that aims to investigate the myopia development after topical application of 0.01% atropine in children with either fast or slow myopia progression classified according to their initial electro-retinal responses. This will help elucidate the effectiveness of using low concentration atropine for myopia control in children with different myopia progression rates.** All of the participated children will be allocated into fast or slow myopia progression group in accordance with the electro-retinal activities as measured by our established protocol from my GRF 2013 study. This protocol also enables us to find out how the retinal electrophysiological changes under the atropine treatment over a 24-month period. The characteristics of these retinal activities will help us to understand the retinal contribution to myopia development in human eye. Furthermore, it will advance our clinical decision to prescribe an appropriate myopia control treatment and be beneficial for the design of a highly effective treatment protocol for myopia control.

Subjects

Based on the study of ATOM2 (Chia et al., 2012), the mean myopia progression rate under 0.01% atropine was -0.49 ± 0.63 D and the mean myopia progression rate in control was -1.20 ± 0.69 D). Hence, 9 subjects should be required for this project to demonstrate the effect of atropine on myopia control (type I error of 5% and the power of 80%; effect size = 1.07, two-tailed; paired group; GPower 3.1). However, based on the mfERG data of our pilot study (Figure 1), the mean inner retinal responses from fast and slow myopia progression group are 67.04 ± 30.54 uV/deg² and 80.61 ± 27.24 uV/deg², therefore the proposed study requires 38 subjects (type I error of 5% and the power of 80%; effect size = 0.47, two-tailed; paired group; GPower 3.1). Assume that the dropout rate of this study throughout the 2-year period is around 5% (according to our preliminary result from my GRF 2013 study) and after consolidation of both analyses, at least 40 subjects aged from 8 to 9 years will be recruited. Children at this age range are believed to be the group with the highest chance of myopia progression. As this study is a randomized controlled trial with two arms, one is the treatment arm and the other one is placebo arm. We will recruit 80 subjects in this study. All of them will receive an ophthalmic assessment including history taking, preliminary tests, objective and subjective refraction, external and internal ocular health assessments. The subjects who meet the following criteria will be recruited to participate in this study. The subjects must have the refractive error between -0.5D and -1D in both eyes and with the best-corrected visual acuity of logMAR 0.00 or better, normal color vision and ocular health. Subjects with any ocular disease, systemic disease and current or history of epilepsy will be excluded from the study.