Myopia Control Effectiveness of Second-generation Defocus Incorporated Multiple Segments Spectacle lenses on Fast Progressing Myopes: Study Protocol of a Randomized Control Trial (Phase 1)

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Purpose

Defocus Incorporated Multiple Segments (DIMS) spectacle lenses for myopia control are appealing to parents and children because of their noninvasive nature. However, their long-term efficacy has room for improvement. There is also limited evidence on their efficacy for high-risk children with early-onset or fast-progressing myopia. A second-generation DIMS design is developed and clinically tested to address these

gaps.

We describe the protocol of a double-masked, placebo-controlled, randomized trial to evaluate the efficacy of second-generation DIMS spectacle lenses in slowing myopia progression in children with early-onset or fast-progressing myopia.

Methods

Chinese schoolchildren aged 4 to 12 years with myopia (spherical equivalent refractive error (SER)) of at least -0.75 diopter (D) in both eyes and with fast progression (≥ 0.50 D per year) or fast axial growth (≥ 0.27 mm per year) in either or both eyes will be recruited. The study consists of a placebo-controlled two-arm trial in the first phase and an auxiliary arm in the second phase. This protocol focuses on Phase 1. Subjects will be randomly allocated in a 1:1 ratio to either arm at baseline. Subjects in the experimental arm will wear second-generation DIMS lenses, while those in the placebo arm will wear single-vision lenses. The subject will undergo cycloplegic assessments every six months throughout the two-year study period. At the end of the first year, subjects in the placebo arm will receive the treatment lens in the second year, and all subjects will continue to be followed during the second year. In phase 2 of the trial, subjects in the auxiliary arm will wear marketed DIMS lenses for two years.

The main outcomes are the changes in cycloplegic SER and axial length over 12 months from baseline. Peripheral refraction and choroidal thickness will also be measured, and their predictive value for myopia control efficacy will be explored. Safety, tolerability, and compliance with the treatment will be closely monitored at each follow-up visit.

Conclusions

This study will provide evidence on the efficacy of the second-generation DIMS technology in controlling myopia in children with early-onset and fast-progressing myopia, facilitating evidence-based practice for myopia management.

Trial registration number: NCT05888792