ISRCTN28611140 https://doi.org/10.1186/ISRCTN28611140

Myopia control trial with progressive addition lenses in Japanese schoolchildren

Submission date	Recruitment status	[_] Prospectively registered
28/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/10/2022	Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Satoshi Hasebe

Contact details
Department of Ophthalmology
Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences
2-5-1 Shikata-cho
Okayama
Japan
700-8558
+81 (86) 235 7297
shasebe@md.okayama-u.ac.jp

Additional identifiers

Protocol serial number
C15390532

Study information

Scientific Title
Myopia control trial with progressive addition lenses in Japanese schoolchildren

Study objectives
That progressive addition lenses slow myopia progression and axial length elongation in myopic children, compared with single-focus lenses

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the ethics panel of Okayama University Medical School on the 21st May 2002 (ref: 105).

Study design
Randomised double-masked placebo-controlled cross-over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Early-onset myopia

Interventions
Full-time wearing progressive addition lenses with near addition power of 1.50D (SOLA Myopia Control [MC] lens, Sola International) versus control group receiving single focus lenses.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Cycloplegic autorefraction (D).

Key secondary outcome(s))
Axial length measurement (mm).

Completion date
10/07/2006

Eligibility

Key inclusion criteria
1. Experience of wearing spectacles to correct myopia
2. Non-cycloplegic autorefraction (Spherical Equivalent [SE]) from -6.00 to -1.25 D
3. Astigmatism less than 1.50 D
4. Aniseiconia less than 1.50 D
5. Best-corrected visual acuity more than 20/20

6. No manifest strabismus with refractive correction
7. Birth weight more than 1250 g
8. No eye disease except for refractive errors
9. No experience of wearing progressive addition lenses or contact lenses

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Appearance of manifest strabismus under refractive correction.

Date of first enrolment
01/07/2002

Date of final enrolment
10/07/2006

Locations

Countries of recruitment
Japan

Study participating centre
Department of Ophthalmology
Okayama
Japan
700-8558

Sponsor information

Organisation
Japanese Ministry of Education, Culture, Sports Science, and Technology (Japan)

ROR
https://ror.org/048rj2z13

Funder(s)

Funder type
Government

Funder Name
Japanese Ministry of Education, Culture, Sports and Technology (Japan) - Scientific research (C)

Funder Name
Tanaka-Chain Optical Company (Japan)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2005		Yes	No
Results article		01/07/2008		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes