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Myopia control trial with progressive addition lenses in Japanese schoolchildren

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://ww3.tiki.ne.jp/~hamaichi/ophthalmology/

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
Cycloplegic autorefraction (D).

Secondary outcome measures
Axial length measurement (mm).

Overall study start date
01/07/2002

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

Age group
Child

Sex
Both

Target number of participants
95

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)

Sponsor details
2-5-1 Marunouchi
Chiyodaku
Tokyo
Japan
100-8959
-
voice@mext.go.jp

Sponsor type
Government

Website
http://www.mext.go.jp/english/index.htm

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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