

# Myopia control trial with progressive addition lenses in Japanese schoolchildren

<b>Submission date</b> 28/06/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/10/2022	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

**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**  
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## 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?
<a href="#">Results article</a>		01/01/2005		Yes	No
<a href="#">Results article</a>		01/07/2008		Yes	No