

# RCT to assess effects of undercorrection or full correction of hypermetropic & astigmatic refractive errors in children on time to optimum acuity, change in refractive error, compliance & acceptance of glasses & achievement of normal vision at 1 year

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/04/2013	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**

N0199157881

## Study information

### Scientific Title

### Study objectives

To assess effects of initial undercorrection or full correction of hypermetropic & astigmatic refractive errors in children on time to optimum acuity, change in refractive error, compliance & acceptance of glasses & achievement of normal vision at 1 year

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Added 05/09/08: Berkshire Research Ethics Committee (UK) ref 05/Q1602/21, 11/03/ 2005, approval renewed 2/.08/08.

### Study design

Double masked randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Not Specified

### Health condition(s) or problem(s) studied

Eye Diseases: Hypermetropia

### Interventions

Trial status amended to 'stopped' as of 05/04/2013 due to notification of lack of funding.

Initial undercorrection vs full correction

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome(s)

Time to optimum acuity, change in refractive error, compliance & acceptance of glasses, achievement of normal vision at one year.

### Key secondary outcome(s))

No secondary outcome measures

### Completion date

31/12/2010

**Reason abandoned (if study stopped)**

Lack of funding/sponsorship

## **Eligibility**

**Key inclusion criteria**

Opportunistic sample of children aged between 3.5 and 6 years with simple hypermetropia and /or astigmatism as their only ocular diagnosis

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

3.5 years

**Upper age limit**

6 years

**Sex**

Not Specified

**Key exclusion criteria**

Manifest strabismus excluding non-accommodative microtropia and extropia, amblyopia which needs occlusion treatment.

**Date of first enrolment**

12/03/2005

**Date of final enrolment**

31/12/2010

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Department of Orthoptics**  
Reading  
United Kingdom  
RG1 5AN

## Sponsor information

**Organisation**  
Department of Health

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Royal Berkshire and Battle Hospitals NHS Trust (UK)

## Results and Publications

**Individual participant data (IPD) sharing plan**

**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="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes