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# 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

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|---|---|---|
| **Submission date**<br>30/09/2005 | **Recruitment status**<br>Stopped | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>30/09/2005 | **Overall study status**<br>Stopped | |
| **Last Edited**<br>05/04/2013 | **Condition category**<br>Eye Diseases | |

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
12/03/2005

### 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

### Age group
Child

### Lower age limit
3.5 Years

### Upper age limit
6 Years

### Sex
Not Specified

### Target number of participants
Target 40 subjects assigned to 'Full Correction' group and 40 subjects assigned to 'Undercorrection' group.

### 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
England

United Kingdom

### Study participating centre
**Department of Orthoptics**
Reading
United Kingdom
RG1 5AN

## Sponsor information

### Organisation
Department of Health

### Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
+44 (0)20 7307 2622
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### Sponsor type
Government

### Website
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

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

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

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

**IPD sharing plan summary**
Not provided at time of registration