ISRCTN12271374 https://doi.org/10.1186/ISRCTN12271374

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

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

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