

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
Registration date 30/09/2005	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 05/04/2013	Condition category Eye Diseases	☐ Individual participant data ☐ 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.

Primary study design

Interventional

Study design

Double masked randomised controlled trial

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