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Improvement in focus during treatment of amblyopia

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/04/2014	Eye Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0280149492

Study information

Scientific Title

Study objectives
Is it possible to improve focus as well as vision during treatment of amblyopia? To identify any effect on efficiency of patching to improve vision.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Eye Diseases: Amblyopia

Interventions
Group 1 = patching treatment with glasses
Group 2 = patching treatment without glasses

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Measure of the focus (refractive error) at 2, 5 and 11 months.

Secondary outcome measures
Visual acuity assessment monthly during patching treatment.

Overall study start date
15/03/2004

Completion date
14/03/2006

Eligibility

Key inclusion criteria
Children with low to moderate hypermetropia and strabismus requiring patching treatment for amblyopia

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
Sample: 180 in total

Key exclusion criteria
1. Anisometropia without strabismus
2. Vision better than 6/18 in the amblyopic eye
3. Anisometropia of less than .5 diopter
4. Child more than 5 years of age
5. Astigmatism of greater than 1.5 diopters
6. Ocular co-morbidity

Date of first enrolment
15/03/2004

Date of final enrolment
14/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant Ophthalmologist
Wirral

United Kingdom
CH49 5PE

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Wirral Hospitals NHS Trust (UK), NHS Research and Development Support Funding

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