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Can patching be improved in lazy eye treatment?

Submission date	Recruitment status	[_] Prospectively registered
01/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/03/2014	Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Can patching be improved in amblyopia treatment?

Study objectives
Educational/motivational material would improve the compliance with patching treatment.

As of 30/11/2011 the anticipated end date for this trial has been updated. The original date was 31/05/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Leicestershire, Northamtonshire & Rutland Research Ethics Committee (LREC), 03/06/2004, ref: 04/Q2501/32
2. Multi-centre Research Ethics Committee (MREC), 03/06/2004, ref: 04/Q2501/32

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
After wearing optimal glasses for 6 weeks children will be asked to patch for all waking hours for 6 out of 7 days a week for 12 weeks.

Group 1: The participants will receive educational materials. We have designed information booklets which explains the condition (amblyopia) for parents, teachers, brothers/sisters and classmates, advice on patching, a motivational story book for the patient and a quotation booklet. We also have a DVD.
Group 2: No intervention

Update as of 30/11/2011: An amendment was made to also include mointoring of glasses wear.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Compliance measured by Occlusion Dose Monitor (ODM) for the entire period of patching (3 months).

Key secondary outcome(s)
Difference in percentage increase of VA between Group 1 and 2 at the end of 12 weeks treatment period.

Completion date
31/05/2012

Eligibility

Key inclusion criteria
1. Children, both males and females, able to perform Glasgow visual acuity test (age 3 - 8 years)
2. Newly detected strabismic, mixed or anisometropic amblyopia (anisometropia = difference >0.5 spherical equivalent or >1.5 diopters for astigmatism) with 0.3 or more logmar difference in visual acuity (VA) between the amblyopic and dominant eye

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
8 Years

Sex
All

Key exclusion criteria
1. Children who have other ophthalmic or neurological diseases
2. Premature children

Date of first enrolment
02/08/2004

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leicester
Leicester
United Kingdom
LE2 7LX

Sponsor information

Organisation
University Hospitals of Leicester NHS trust (UHL) (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
National Eye Research Centre (NERC) (UK)

Alternative Name(s)
National Eye Research Centre, SightResearchUK, SRUK, NERC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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?
Results article	results	01/07/2014		Yes	No