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Can patching be improved in lazy eye treatment?

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Difference in percentage increase of VA between Group 1 and 2 at the end of 12 weeks treatment period.

Overall study start date
02/08/2004

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

Age group
Child

Lower age limit
3 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
60

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
England

United Kingdom

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

Sponsor information

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

Sponsor details
Trust Headquarters
Gwendolen House
Gwendolen Road
Leicester
England
United Kingdom
LE5 4QF

Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014		Yes	No