

# Can patching be improved in lazy eye treatment?

<b>Submission date</b> 01/04/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/03/2014	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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, Northamptonshire & 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 monitoring 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?
<a href="#">Results article</a>	results	01/07/2014		Yes	No