

# Improvement in focus during treatment of amblyopia

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/04/2014	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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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