

# Optical treatment of nystagmus

<b>Submission date</b> 08/07/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/08/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/06/2015	<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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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 1

## Study information

**Scientific Title**

A quantitative study comparing hard and soft contact lenses to spectacles on changes in nystagmus oscillations

**Study objectives**

Our hypothesis is that nystagmus can be improved with contact lens wearing. The specific research questions are:

1. Do contact lenses reduce nystagmus and improve vision compared to spectacle wearing?
2. Are hard contact lenses better than soft contact lenses for reducing nystagmus and improving vision in nystagmus?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Leicestershire, Northamptonshire and Rutland Research Ethics Committee 1, 06/07/2010, ref: 10/H0406/40

**Study design**

Randomised single-centre unmasked cross-over study

**Primary study design**

Interventional

**Secondary study design**

Randomised cross over trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Nystagmus

**Interventions**

Patients will take part in the trial for a total duration of 8 weeks. This will comprise of 2 weeks of spectacle wear followed by 2 weeks of hard or soft contact lens wear. The next 2 weeks the patients will be wearing the opposite type of contact lens to those prescribed previously and then finally 2 weeks of spectacle wear again. Details of each visit are below:

Visit 1: Optimal refraction determined and glasses prescribed and contact lenses fitted and ordered followed by EXAMINATION 1

Day 1 - 14: Spectacle wearing (minimum of 14 days)

Visit 2 (day 14): EXAMINATION 2 followed by contact lens type 1

Day 15 - 28: Contact lens type 1 wearing

Visit 3 (day 28): EXAMINATION 3 followed by contact lens type 2  
Day 29 - 42: Contact lens type 2 wearing  
Visit 4 (day 42): EXAMINATION 4 followed by spectacle wearing  
Day 43 - 56: Spectacle wearing  
Visit 5 (day 56): EXAMINATION 5

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Changes in nystagmus intensity measured with eye movement recordings, measured at baseline, day 14, day 28, day 42 and day 56.

### **Secondary outcome measures**

Measured at baseline, day 14, day 28, day 42 and day 56:

1. Changes in LogMAR (chart) visual acuity at 4M (with head free)
2. Changes in LogMAR (chart) visual acuity at 0.4M (with head free)
3. Change in gaze dependant visual acuity at 4M
4. Change in nystagmus intensity, NAFX function and reading speed will be evaluated from the eye movement recordings at different fixation points across the horizontal plane
5. Subjective changes in visual function evaluated with the VFQ25

### **Overall study start date**

01/09/2010

### **Completion date**

01/09/2012

## **Eligibility**

### **Key inclusion criteria**

Infantile nystagmus over the age of 16 years, either sex

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

28

### **Key exclusion criteria**

1. Currently involved in surgical or pharmacological trials for the treatment of nystagmus
2. Previous corneal trauma or intolerance to contact lens wearing

**Date of first enrolment**

01/09/2010

**Date of final enrolment**

01/09/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of Leicester**

Leicester

United Kingdom

LE2 7LX

## **Sponsor information**

**Organisation**

University of Leicester (UK)

**Sponsor details**

Faculty of Medicine and Biological Sciences (MSB)

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gjh13@leicester.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.le.ac.uk/sm/le>

**ROR**

<https://ror.org/04h699437>

## Funder(s)

### Funder type

University/education

### Funder Name

University of Leicester (UK)

### Alternative Name(s)

UoL

### 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	01/09/2014		Yes	No