

Optical treatment of nystagmus

Submission date 08/07/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/06/2015	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised single-centre unmasked cross-over study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

01/09/2012

Eligibility

Key inclusion criteria

Infantile nystagmus over the age of 16 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

University of Leicester
Leicester
United Kingdom
LE2 7LX

Sponsor information

Organisation

University of Leicester (UK)

ROR

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

Funder(s)

Funder type

University/education

Funder Name

University of Leicester (UK)

Alternative Name(s)

UniofLeicester, UoL

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

results

01/09/2014

Yes

No