ISRCTN80219391 https://doi.org/10.1186/ISRCTN80219391

Optical treatment of nystagmus

Submission date 08/07/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/08/2010	**Overall study status** Completed	
Last Edited 02/06/2015	**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

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 nystgamus 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 intolerence 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?

Results article	results	01/09/2014	Yes	No