ISRCTN58592532 https://doi.org/10.1186/ISRCTN58592532

The pharmacological treatment of nystagmus

Submission date 09/10/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 05/12/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/08/2017	**Condition category** Eye Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Nystagmus is an involuntary to and fro movement of the eyes that causes reduced vision. Nystagmus can be acquired in later life, due to neurological disease, or acquired in infancy (infantile nystagmus). There are drugs available to treat nystagmus but there are very few studies to show how effective these medications are. Following on from the use of gabapentin and memantine in acquired nystagmus, we aim to assess whether gabapentin and memantine improve visual acuity and eye movement in infantile nystagmus.

Who can participate?
Patients over the age of 16 years with nystagmus.

What does the study involve?
The study is of a crossover design which means each participant will receive all three treatments (gabapentin, memantine and placebo [dummy drug]) in a random order. Each phase of medication is administered for 17 weeks and there will be a 6-week washout period in between each new treatment. During each phase of medication we will examine the participants five times while the medication is at differing doses. We will examine visual function and eye movement and administer a visual functioning questionnaire at each visit. There will be a total of 16 visits over 69 weeks.

What are the possible benefits and risks of participating?
Possible benefits may be an improvement in vision and/or eye movement. There may also be no direct benefit to the participants but the results may help determine how we treat people with nystagmus in the future. As with any study using medication there may me some unwanted side effects; the most common side effects for gabapentin are drowsiness, dizziness and fatigue and for memantine dizziness, drowsiness and headache.

Where is the study run from?
University of Leicester (UK).

When is the study starting and how long is it expected to run for?
From January 2008 to January 2013.

Who is funding the study?
The Childrens Research Fund (UK).

Who is the main contact?
Prof Irene Gottlob
ig15@le.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Irene Gottlob

Contact details
University of Leicester
Ophthalmology Group
RKCSB
Leicester Royal Infirmary
Leicester
United Kingdom
LE2 7LX
+44 (0)116 258 6291
ig15@le.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2 October 2007

Study information

Scientific Title
Pharmacological treatment of nystagmus: a randomised double-masked, placebo-controlled crossover study using gabapentin and memantine

Study objectives
Nystagmus consists of involuntary to and fro eye movements and severely affects visual function. It occurs in approximately 2.4 in 1000 people. It can be congenital idiopathic, due to retinal diseases and low vision, or associated with neurological diseases. Nystagmus is one of the most distressing eye disorders with symptoms causing blurred vision and oscillopsia (illusory motion of the environment). To date, there is little knowledge in the treatment of nystagmus.

Our hypothesis is that congenital and acquired nystagmus can be treated pharmacologically.

Research questions:
1. How do memantine and gabapentin compare for treatment of nystagmus?
2. Is there a specific nystagmus form, which responds better to pharmacological treatment with memantine or gabapentin?

Please note that the pilot study to this trial is assigned to ISRCTN65414827: Pharmacological Treatment of Congenital Nystagmus (see http://www.controlled-trials.com/ISRCTN65414827).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration – submission pending

Study design
Randomised single-centre double-masked placebo-controlled crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
180 patients with nystagmus (45 with Idiopathic Infantile Nystagmus [IIN], 45 with nystagmus secondary to albinism, 45 with nystagmus secondary to other eye diseases and 45 with acquired nystagmus) were recruited.

Gabapentin, memantine and placebo will be administered (orally) in random order with 6 week wash out periods in between according to the following scheme:

1. Gabapentin (300 mg units):
Day 0: Examination
Day 1 - 5: 600 mg/day in two divided doses
Day 6 - 10: 900 mg/day in three divided doses
Day 11 - 15: 1200 mg/day in three divided doses
Day 15: Examination
Day 16 - 57: 1200 mg/day in three divided doses

Day 57: Examination
Day 58 - 62: 1500 mg/day in three divided doses
Day 63 - 67: 1800 mg/day in three divided doses
Day 68 - 72: 2100 mg/day in three divided doses
Day 73 - 77: 2400 mg/day in three divided doses
Day 77: Examination
Day 78 - 119: 2400 mg/day in three divided doses
Day 119: Examination

2. Memantine (5 mg units):
Day 0: Examination
Day 1 - 5: 10 mg/day in two divided doses
Day 6 - 10: 15 mg/day in three divided doses
Day 11 - 15: 20 mg/day in three divided doses
Day 15: Examination
Day 16 - 57: 20 mg/day in three divided doses
Day 57: Examination
Day 58 - 62: 25 mg/day in three divided doses
Day 63 - 67: 30 mg/day in three divided doses
Day 68 - 72: 35 mg/day in three divided doses
Day 73 - 77: 40 mg/day in three divided doses
Day 77: Examination
Day 78 - 119: 40 mg/day in three divided doses
Day 119: Examination

Placebo will follow the same regime. The same number of capsules will be administered as the active medication at each point in the scheme.

Total duration time of all treatment arms and washout periods will be 483 days (119 per drug with a washout period of 42 days per drug). Patients will be followed up at just 6 weeks after taking the last medication of the final arm to which they are randomised.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gabapentin, memantine

Primary outcome measure
Change in distance in Logarithm of the Minimum Angle of Resolution (LogMAR) visual acuity between memantine, gabapentin and placebo.

Each of the primary and secondary outcomes will be measured at day 0, 15, 57, 77 and 119 of each treatment arm.

Secondary outcome measures
1. Change in near LogMAR visual acuity between memantine, gabapentin and placebo
2. Change in nystagmus intensity (expanded Nystagmus Acuity Function [NAFX]) function and

reading speed will be evaluated as described above at 1.2 m for the different fixation points tested and at near for null point between memantine and gabapentin and placebo
3. Subjective changes in visual function by self-assessment on Visual Function 14 (VF14) questionnaire between memantine and gabapentin and placebo

Each of the primary and secondary outcomes will be measured at day 0, 15, 57, 77 and 119 of each treatment arm.

Overall study start date
01/01/2008

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Patients with congenital or acquired nystagmus
2. Over the age of 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180 patients with nystagmus

Key exclusion criteria
1. Contraindication for gabapentin or memantine such as epilepsy, renal impairment, pregnancy or breast-feeding
2. For women of childbearing potential, a pregnancy test will be performed and documentation of adequate contraception during the study drug administration will be obtained
3. Patients on medication incompatible with gabapentin or memantine, such as amantadin

Date of first enrolment
01/02/2011

Date of final enrolment
01/11/2012

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 (UK)

Sponsor details
c/o John Hampton
Research and Development
Leicester General Hospital
Leicester
England
United Kingdom
LE5 4PW
+44 (0)116 249 0490
john.hampton@uhl-tr.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
The Childrens Research Fund (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available