ISRCTN57618066 https://doi.org/10.1186/ISRCTN57618066

Cross-over comparison of gabapentin and memantine as treatment for acquired nystagmus

Submission date	Recruitment status	[_] Prospectively registered
23/06/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/08/2019	Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr R John Leigh

Contact details
Neurology (127W)
Louis Stokes Department
Veterans Affairs Medical Center
10701 East Boulevard
Cleveland, Ohio
United States of America
44106-1702
-
rjl4@case.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2003-057

Study information

Scientific Title
Comparison of gabapentin and memantine as treatment for acquired nystagmus: a double-blind cross-over study with each patient serving as their own control

Study objectives
To compare the therapeutic effects of gabapentin versus memantine at treatment for acquired nystagmus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Cleveland Veterans Affairs Medical Center Institutional Review Board approved on the 22nd June 2004
2. US Food and Drug Adminstration approved on the 8th January 2004 (ref: CPA #521)

Study design
Double-blind cross-over study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact rjl4@case.edu to request a patient information sheet

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

Interventions
Gabapentin will be given at a starting dose of 1 capsule (300 mg) per day for 3 days; then 1 capsule twice per day for 3 days; then 1 capsule three times per day for 3 days, and finally 1 capsule four times per day (total = 1200 mg/day) for the final remaining 5 days. The final evaluation of vision and eye movements will be made during the 14th day of taking gabapentin. Memantine will be given at a starting dose of 1 capsule (10 mg) per day for 3 days; then 1 capsule twice per day for 3 days; then 1 capsule three times per day for 3 days, and finally 1 capsule four times per day (total = 40 mg/day) for the final remaining 5 days. The final evaluation

of vision and eye movements will be made during the 14th day of taking memantine. Side effects of each medication will be monitored with a provision for holding at the maximum dose of the drug that the patient can tolerate for the duration of the study.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
1. Visual acuity of each eye, measured at far or near prior to, and on the final day of, treatment with each drug
2. Median eye speed, measured with the magnetic search coil technique, prior to, and on the final day of, treatment with each drug

Measured at the end of 14 days on each medicine.

Secondary outcome measures
The patient's overall assessment of whether either drug improves their vision and is generally well tolerated, measured at the end of 14 days on each medicine.

Overall study start date
22/06/2004

Completion date
22/06/2009

Eligibility

Key inclusion criteria
1. Patients with acquired nystagmus due to multiple sclerosis, stroke (brain stem) or cerebellar disease (such as Chiari malformation)
2. Medically stable
3. Able to give informed consent
4. Can understand and cooperate with the testing
5. Aged 18 years or older, both sexes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
1. Not able to understand or follow the instructions of each protocol
2. Too frail to sit in the vestibular chair during testing for the required period
3. Judged to be at risk for falls (many patients with poor balance adjust to this, and are not at risk of falls)
4. History of mental illness or confusion
5. Known to have an allergy to gabapentin or memantine
6. Pregnant, since the safety of memantine in pregnancy is unknown

Date of first enrolment
22/06/2004

Date of final enrolment
22/06/2009

Locations

Countries of recruitment
United States of America

Study participating centre
Neurology (127W)
Cleveland, Ohio
United States of America
44106-1702

Sponsor information

Organisation
National Eye Institute/National Institutes of Health (USA)

Sponsor details
2020 Vision Place
Bethesda
United States of America
MD 20892-3655

+1 301 496 5248
2020@nei.nih.gov

Sponsor type
Government

Website
http://www.nei.nih.gov/

ROR
https://ror.org/03wkg3b53

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (NIH) (USA) (ref: R01-EY06717)

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

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?
Results article	results	01/05/2010	08/08/2019	Yes	No