

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

<b>Submission date</b> 23/06/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/08/2019	<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

### Protocol serial number

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 Administration approved on the 8th January 2004 (ref: CPA #521)

**Study design**

Double-blind cross-over study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**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(s)**

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.

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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)

**ROR**

<https://ror.org/03wkg3b53>

## Funder(s)

**Funder type**

Government

**Funder Name**

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

**Alternative Name(s)**

US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

## Location

United States of America

# 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?
<a href="#">Results article</a>	results	01/05/2010	08/08/2019	Yes	No