Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of memantine on visual acuity of patients with optic neuritis

Protocol summary

Summary
This study is performed aimed to evaluate the efficacy of memantine in patients with optic neuritis referred to Imam Khomeini Hospital . This study is a randomized, double-blind, placebo-controlled, single-center. The subjects included all patients with a first episode of acute optic neuritis. Inclusion criteria: age range 18 to 46 years, the first attack of acute optic neuritis with visual symptoms of 8 days duration or less . Exclusion criteria: lack of diagnostic criteria of multiple sclerosis, negative history of immunosuppressive drugs , no history of ophthalmic problems or surgery. The sample size is 64 patient,32 patients for each case and control groups. required intervention is Administration of memantine and placebo, That will be performed after adminstration of prednisone as an standard treatment of acute phase. The primary outcome is to improve visual acuity in both control and intervention groups.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2017042633647N1**
Registration date: **2017-10-20, 1396/07/28**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2017-10-20, 1396/07/28

Registrant information
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Recruitment status
Recruitment complete
Funding source
Investigator

Expected recruitment start date
2016-03-19, 1394/12/29
Expected recruitment end date
2017-08-22, 1396/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of memantine on visual acuity of patients with optic neuritis

Public title
The effect of memantine in the treatment of optic neuritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age range 18 to 46 years; the first attack of acute optic neuritis with visual symptoms of 8 days duration or less . Exclusion criteria: lack of diagnostic criteria of multiple sclerosis; negative history of immunosuppressive drugs ; no history of ophthalmic problems or surgery.
Age
From **18 years** old to **46 years** old
Gender
Male

Phase
N/A

Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
randomization in this study was performed using a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Science
Street address
Imam Khomirni hospital, keshavarz blv, Tehran
City
Tehran
Postal code
1419733141
Approval date
2016-04-09, 1395/01/21
Ethics committee reference number
IR.TUMS.REC.1395.2331

Health conditions studied

1

Description of health condition studied
Optin Neuritis
ICD-10 code
H46
ICD-10 code description
neuropathy, except ischaemic

Primary outcomes

1

Description
Visual Acuity
Timepoint
Start of study, 3 Month after treatment
Method of measurement
Snelen chart

Secondary outcomes

1

Description
Visual Evoked Potential
Timepoint
Start of Study, 3 Month after treatment
Method of measurement
with Visual Evoked Potential instrument

Intervention groups

1

Description
Group Intervention: Memantine tablets 10 mg once daily, for three months.
Category
Treatment - Drugs

2

Description
Control group : placebo Designed by memantine company manufactures with same packaging.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomirni hospital
Full name of responsible person
Dina Motamedi
Street address
Imam Khomirni hospital, keshavarz blv, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Sarraf Payam
Street address
Central university organization , Keshavarz blv
City
Tehran
Grant name
-
Grant code / Reference number
-

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty