Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of Repetetive Transcranial Magnetic Stimulation(RTMS) on Mild Cognitive Impairment (MCI)

Protocol summary

Summary

The aim of this study is to compare the effect of repetitive trans cranial magnetic stimulation (RTMS) and placebo on mild cognitive impairment (MCI). The study is a not blinded, cross over and self-controlled clinical trial. 16 people, including men and women from Firoozgar and Rasool hospitals, affiliated to Iran University of Medical Sciences, who complain of memory impairment will be recruited to the study. The inclusion criteria is mild cognitive impairment based on MMSE(MiniMental Status Examination) and MCA(Montreal Cognitive impairment) tests .Treatable causes of dementia will be excluded from the study . Patients will be divided into two groups .The first group will receive RTMS while second group will receive Placebo. After 8 weeks two groups will be assessed and crossed over. First group will receive placebo and second group will receive RTMS up to 8 weeks. MMSE & MCA will be performed and compared after each 8 weeks. This study will be performed in a five months

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011028199N2**
Registration date: **2017-04-27, 1396/02/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-27, 1396/02/07

Registrant information

Name

Ensieh Malekdar

Name of organization / entity

Iran Univercity of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Repetetive Transcranial Magnetic Stimulation(RTMS) on Mild Cognitive Impairment (MCI)

Public title

Effect of Repetetive Transcranial Magnetic Stimulation(RTMS) on Mild Cognitive Impairment (MCI)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Patients with MCI(mild cognitive impairement) based on complaint of memory impairment with MMSE(mini mental status exam) score of more than 24 / 30 ؛ MCA(Montreal Cognitive Asessment)score of more than 26 / 30. Exclusion criteria : Dementia confirmed with MMSE score of less than 24 /30؛ MCA score of less than 26 / 30 ؛Other treatable causes of dementia including serum B12 level below 200 Pg/ml ؛

hypothyroidism with thyroid stimulating hormone of above 6 uU/ml؛ any lesion on brain computed tomography scan explaining forgetfulness ؛ Depression rolled out in the recruited population with Beck screening test 14-28.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **16**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features
We will use Closed Packet in both intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
,Shahid Hemmat Highway .Tehran,1449614535,IRAN

City
Tehran

Postal code
1449614535

Approval date
2015-06-14, 1394/03/24

Ethics committee reference number
IR.IUMS.REC.1394.9211158008

Health conditions studied

1

Description of health condition studied
Mild cognitive disorder

ICD-10 code
F06.7

ICD-10 code description
Mild cognitive disorder

Primary outcomes

1

Description
Evaluation of change in cognitive function

Timepoint
From one week before intervention & placebo to one week after intervention & placebo

Method of measurement
Questionnaire includes Mini Mental Cognitive Exam and Montreal Cognitive Assessment

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Intervention group 1: 8 patients in this study will be treated with RTMS 2-3 times per week for 8 weeks with every session lasts for 30 minutes. Device for induction of magnitude wave is named Magnature which is made in Denmark .the frequency is above 1 Hz and usually above 10 Hz which has the optimal stimulation effect on postero-lateral prefrontal cortex. Intensity: The intensity is the minimum stimulation which is required to induce contraction of small hand muscles observed by a physician or recorded by an electromyogram. This intensity is usually 100 to 120 percent of resting membrane potential of a neuron. Time of stimulation: 10 seconds. Location of stimulation: left dorsolateral prefrontal cortex which is related to memory. Interval of stimulations: 0.20 seconds. Number of stimulation in every sessions: 1000 Time of every session: 30 minutes Number of sessions: 2-3 sessions per week, up to 8 weeks. The treated group are subsequently treated with placebo for the next 8 sessions via voice without magnitude after mentioned cognitive tests (Mini-Mental State Exam & Montreal Cognitive Assessment) being performed Cognitive tests will be performed for both groups at the end of the last session

Category
Treatment - Devices

2

Description
Intervention group 2: 8 patients will be initially treated with placebo for 8 weeks via pure voice without real

magnitude wave cognitive tests. Cognitive tests will be performed at the end of the 8th week. The mentioned group will later be treated by real magnitude wave for 8 weeks and mentioned cognitive tests will be repeated

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Ensieh Malekdar, Neurology student, Iran University of Medical Science

Street address

Valadee street, Valiasr square, Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Rasoole akram hospital

Full name of responsible person

Ensieh Malekdar,Neurology student, Iran university of Medical Science

Street address

Niaiesh street, Sattarkhan street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research of Iran University of Medical Science

Full name of responsible person

Doctor Masood Mehrpour

Street address

beside Milad hospital, Hemmat highway, Tehran

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 of Iran University of Medical Science

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

Firoozgar hospital

Full name of responsible person

Ensieh Malekdar

Position

4th years resident in Neurology feild

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Firoozgar hospital

Full name of responsible person

Dr.Masood Mehrpour

Position

Head of stroke center, Firoozgar Hospital, Associate professor,Neuronterventionist

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work
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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