Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of the Effectiveness of Repetitive Transcranial Magnetic Stimulation(rTMS) on severity of Delirium in Delirious Patients.

Protocol summary

Study aim
Study of Effectiveness of Repetitive Transcranial Magnetic Stimulation(rTMS) on severity of Delirium.

Design
30 Delirious patients admitted to Rasoul-e-Akram Hospital, who were under psychiatric counseling, were randomly divided into two intervention and control groups

Settings and conduct
The site of the study is the Rasoul-e-Akram Hospital.The intervention group received a rTMS session, while the control group was treated with sham.Delirium severity is evaluated 15 minutes before and after magnetic stimulation evaluator and participants are not aware of intervention and control group.

Participants/Inclusion and exclusion criteria
Inclusion Criteria is Delirium diagnosis and being up to 18 years ;Exclusion Criteria is prohibited Cases of rTMS ,like Brain Tumor and Head Trauma .

Intervention groups
Intervention group,delirious patients that one session receive rTMS; Control group is treated with Sham with the same appearance of coil

Main outcome variables
Delirium Severity

General information

Reason for update

Acronym
rTMS Repetitive Transcranial Magnetic Stimulation

IRCT registration information
IRCT registration number: **IRCT20171223038019N1**
Registration date: **2018-04-02, 1397/01/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-02, 1397/01/13**
Update count: **0**

Registration date
2018-04-02, 1397/01/13

Registrant information

Name
Emad Yaghoubi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-01, 1396/12/10

Expected recruitment end date
2018-07-21, 1397/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the Effectiveness of Repetitive Transcranial Magnetic Stimulation(rTMS) on severity of Delirium in Delirious Patients.

Public title
Effect of rTMS on severity of Delirium

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Delirium Assessment with both Criteria CAM and DSM 5
Not Head Trauma in the one past year Admit in non-

psychiatric wards Over 18 years old age Informed Consent to participate in study

Exclusion criteria:

Doubt about Cerebrovascular accident History of myocardial infarction, Heart valve surgery, Atrial fibrillation rhythm Impaired cranial nerve examination Asymmetry deep tendon reflex Pupiledema History of Dementia Intubation patients Opium or alcohol withdrawal syndrome Metal piece or Pacemaker in body Brain tumor History of Seizure

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization from permuted block randomization that the measure of blocks chosen randomly,allocation concealment by using of sequentially numbered ,sealed,opaque envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

Project Participation and Delirium severity valuator are not informed of intervention and control groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Science

Street address

Medical College, Near Milad Tower, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-10-11, 1396/07/19

Ethics committee reference number

IR.IUMS.FMD.REC1396.9411286017

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes

1

Description

Delirium severity

Timepoint

15 minutes before intervention and 15 minutes after intervention

Method of measurement

NEECHAM Confusion Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group receive only one rTMS session, which is performed between 9 to 13 O'clock,Delirium severity is evaluated 15 minutes before and 15 minutes after intervention based on NEECHAM scale.Magnetic stimulation is performed in the left dorsolateral prefrontal cortex with a theta burst.burst pulse3.interpulse interval 20 millisecond frequency 5. The machine is made by magventure company and its model is Mag pro X100.

Category

Treatment - Devices

2

Description

Control group: As the intervention group, they receive a rTMS session, but instead of the active coil, they are treated with the sham that looks like coil.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasul Akram hospital

Full name of responsible person
Emad Yaghoubi

Street address
Rasul Akram hospital, Maziyar Mansouri St, Sattarkhan Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Deputy of Research of Iran University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Emad yaghoubi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Person responsible for scientific inquiries

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Full name of responsible person
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Specialist

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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available