

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 26 3663 3181

Email address

dr.emadyaghoubi@irimc.org

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 pulse 3. 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, Mazyar Mansouri St,
Sattarkhan Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2360

Email

dr.emadyaghoubi@yahoo.com

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

Street address

Iran University of Medical Science, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

research@iums.ac.ir

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

Street address

Rasul Akram hospital, Mazyar Mansouri St, Sattarkhan
Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 64352360

Email

dr.emadyaghoubi@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Atefeh Ghanbari Jolfaei

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Rasul Akram hospital, Mazyar Mansouri St. Sattarkhan
Ave.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2313

Email

draghj@yahoo.com

Person responsible for updating data

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

Street address

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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