Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Comparison of effectiveness of repetitive TMS and iTBS on negative Symptoms and Cognition in Patients with Schizophrenia:a study randomized and double blind

Protocol summary

Summary

The aim of this study is to investigate the effect of repetitive TMS and theta burst in reduction of negative symptoms and remission of cognitive functioning in patients with schizophrenia. In a randomized, double blind clinical trials, 30 patients with schizophrenia in Razi psychiatric hospital will be assigned to receive repetitive TMS, theta burst, or sham TMS, daily; for 20 sessions. The negative symptoms and cognitive functioning will be assessed before the treatment (pre test) during the treatment (10th session), and after the treatment (post test).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903254191N1**
Registration date: **2011-01-09, 1389/10/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-01-09, 1389/10/19

Registrant information

Name
Reza Kazemi
Name of organization / entity
University of Tehran
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Atieh comprehensive psyche and nerve center

Expected recruitment start date

2011-01-05, 1389/10/15

Expected recruitment end date

2011-07-21, 1390/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of effectiveness of repetitive TMS and iTBS on negative Symptoms and Cognition in Patients with Schizophrenia:a study randomized and double blind

Public title

Repetitive transcranial magnetic stimulation and intermittent theta burst stimulation in schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: outpatients male and female with the range of 18-50 years of age, The diagnosis of Schizophrenia according to DSM-IV-TR, Completion of Consent Form, Being Under Supervision of a psychiatrist, being able to adhere to treatment Schedule, having stable symptoms as defined by not requiring a change in Antipsychotic medication for at least 4 weeks or at least 2 weeks for psychotropic agents prior to entering the Study Exclusion Criteria: The history of rTMS treatment for any reason, Intracranial Implant and other ferromagnetic materials close to the head, Cardiac Pacemaker, drug Pumps, acute heart attack, the risk of Seizure with any reasons, high Intracranial pressure, The

history of epilepsy or Seizure in the first relatives, any metal in Head, brain trauma, history of loss of consciousness for more than 5 minutes, pregnancy, breastfeeding, drug dependency, high risk of Suicide, significant positive symptoms

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
University of Social wellfare and rehabilitation sciences

Street address
University of Social Wellfare and Rehabilitation Sciences, Kodakyar St, Evin, Tehran, Iran.

City
Tehran

Postal code
1985713834

Approval date
2010-11-07, 1389/08/16

Ethics committee reference number
801/4/89/1786

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
negative symptoms

Timepoint
Session One,Session ten, Session twenty

Method of measurement
Positive and negative symptom scale

2

Description
Cognitive functioning

Timepoint
Sessions One, ten, and twenty

Method of measurement
Neuropsychology Battery Tests

Secondary outcomes

1

Description
Depression

Timepoint
Session One,Session ten, Session twenty

Method of measurement
Calgary depression for schizophrenia scale (CDSS)

2

Description
Quality of life

Timepoint
Session One,Session ten, Session twenty

Method of measurement
Schizophrenia quality of life scale (SQLS)

3

Description
Social Functioning

Timepoint
Sessions One, ten, and twenty

Method of measurement
Social and occupational functioning Assessment scale (SOFAS)

Intervention groups

1

Description
15 Hz rTMS are applied during 20 to 30 minutes in 20 sessions

Category
Treatment - Devices

2

Description
50Hz theta burst ia applied during 5 to 10 minutes in 20 sessions
Category
Treatment - Devices

3

Description
Sham coil in 20 sessions
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
razi psychiatric hospital
Full name of responsible person
Dr.mohammad reza khodaei
Street address
Razi Psychiatric Hospital, University of Social Welfare and Rehabilitation Sciences, Amin Abad, Shahre Rey, Tehran, Iran
City
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2

Recruitment center
Name of recruitment center
Atieh comprehensive psyche and nerve center
Full name of responsible person
Dr. Reza Rostami
Street address
23 No., Vali nezhad St., Vali asr Ave., Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Atieh comprehensive psyche and nerve center
Full name of responsible person
Dr.reza rostami
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23 No., Vali nezhad St., Vali asr Ave., Tehran, Iran
City
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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
Atieh comprehensive psyche and nerve center
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

Person responsible for scientific inquiries

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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