

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8401 2128

Email address

rezakazemi@ut.ac.ir

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 welfare and rehabilitation sciences

Street address

University of Social Welfare 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

tehran

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

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

City

Tehran

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

Contact

Name of organization / entity

University of Tehran

Full name of responsible person

Reza Kazemi

Position

Master of science in clinical psychology

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