

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Intermittent theta-burst trans-cranial magnetic stimulation for autism spectrum disorder: A randomized Controlled Trial

Protocol summary

Study aim

Assessment the efficacy of intermittent theta-burst stimulation to improve the symptoms of patients with ASD

Design

A randomized wait-list control trial with a sample size of 28 subjects and equal allocation between groups. Randomization will be based on the random allocation rule.

Settings and conduct

The study population will be included the children who met the Diagnostic and Statistical Manual of Mental Disorders, fifth edition criteria for diagnosis of ASD. Eligible individuals are divided into two groups of experimental and waiting list. Interventions are performed by 2 trained technicians in Rad Clinic in Tehran and Dr. Hosseini's office in Sari. This study is not blinded. Patients will be evaluated before the intervention, immediately and one months after the end of the sessions by four psychometric instruments.

Participants/Inclusion and exclusion criteria

Inclusion criteria; 1)Autism Spectrum Disorder (ASD) in the age group of 9 to 17 years 2)Mild to moderate ASD 3) Stable clinical condition in the last 2 months 4) Stable treatment schedule in the last 2 months 5) Intelligence quotient of 55 or greater on the Wechsler test Criteria for non-inclusion in the study; 1)Severe ASD 2) Intelligence quotient less than 55 on the Wechsler test 3) History of seizures 4) History of serious head trauma 5) The presence of implants in the brain 6) History of substance abuse

Intervention groups

The experimental group will receive 15 sessions of intermittent theta-burst stimulation over the right dorsolateral prefrontal cortex and in the control group no intervention will be used.

Main outcome variables

Severity of Autism spectrum disorder symptoms based on Autism Behavior Checklist; Severity of obsessive

compulsive symptoms based on score of Yale-Brown Obsessive Compulsive Scale; Selective attention based on Stroop test; Executive function based on Wisconsin Card Sorting test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220204053933N1**

Registration date: **2022-03-13, 1400/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-13, 1400/12/22**

Update count: **0**

Registration date

2022-03-13, 1400/12/22

Registrant information

Name

Seyede Hakime Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 1811

Email address

s.hakime.hashemi64@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-05, 1400/12/14

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intermittent theta-burst trans-cranial magnetic stimulation for autism spectrum disorder: A randomized Controlled Trial

Public title

Intermittent theta-burst stimulation for autism spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with autism spectrum disorder (ASD) aged 9 to 17 years Mild to moderate ASD Stable clinical conditions in the last 2 months Stable treatment schedule in the last 2 months Intelligence quotient of 55 or greater on the Wechsler test

Exclusion criteria:

Patients with severe ASD Intelligence quotient <55 based on Wechsler intelligence test History of seizures History of serious head trauma The presence of implants in the brain History of substance abuse

Age

From **9 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method will be performed. Before the study, 28 sealed envelopes containing treatment information (test or waiting list, with equal allocation) were prepared, and after the start of the study, they were randomly selected for each participant.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

13th floor,Block A, Ministry of Health and Medical Education, Simaye Iran Street, Qods Town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2021-09-08, 1400/06/17

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.634

Health conditions studied**1****Description of health condition studied**

Autism Spectrum Disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes**1****Description**

Severity of Autism Spectrum Disorder Symptoms Based on Autism Behavior Checklist

Timepoint

Evaluation before the intervention, immediately after the end of 15 sessions, one month after the end of the sessions

Method of measurement

Autism Behavior Checklist

2**Description**

Severity of obsessive-compulsive symptoms based on score of Yale-Brown Obsessive Compulsive Scale (YBOCS)

Timepoint

Evaluation before the intervention, immediately after the end of 15 sessions, one month after the end of the sessions

Method of measurement

Yale-Brown Obsessive Compulsive Scale (YBOCS)

3**Description**

Changes in selective attention based on Stroop test

Timepoint

Evaluation before the intervention, immediately after the end of 15 sessions, one month after the end of the sessions

Method of measurement

Stroop test

4

Description

Change in executive function based on Wisconsin Card Sorting Test

Timepoint

Evaluation before the intervention, immediately after the end of 15 sessions, one month after the end of the sessions

Method of measurement

Wisconsin Card Sorting Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 15 theta burst stimulation sessions (one session per day for 3 consecutive weeks) will be conducted for each participant in the intervention group. In this study, electromagnetic excitations on the right dorsolateral prefrontal cortex will be considered. Theta-burst stimulation parameters include: Burst pattern: three pulses delivered at 50Hz Train duration: bursts repeated five times per second (5Hz) for 2s (10 bursts). Intensity: 100% of resting motor threshold. Inter-train interval: 8s. Total time: 300s Total trains: 30. Total bursts: 300. Total pulses: 600

Category

Treatment - Devices

2

Description

Control group: The control group did not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Seyede Hakime Hashemi

Street address

South Kargar Street

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Postal code

13337159140

Phone

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Web page address

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2

Recruitment center

Name of recruitment center

Dr. Seyed Hamzeh Hosseini's office

Full name of responsible person

Seyede Hakime Hashemi

Street address

Berlian Medical Complex, Upper floor of Tejarat Bank, Imam Square

City

Sari

Province

Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Sixth floor, Vice Chancellor for Research and Technology, University Central Organization, Qods St., Keshavarz Boulevard

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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
Tehran University of Medical Sciences
Proportion provided by this source
50
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

2

Sponsor

Name of organization / entity
Cognitive Science and Technologies Council
Full name of responsible person
Seyed Kamal Kharrazi
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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

Cognitive Science and Technologies Council

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences
Full name of responsible person
Dr. Javad Alaghband Rad
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyede Hakime Hashemi

Position

Subspecialty Assistant

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

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City

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Fax**Email**

s.hakime.hashemi64@gmail.com

Web page address**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