Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effect of trans cranial direct current stimulation (TDCS) intervention on improving anxiety, depression, quality of life, and severity of symptom in patients with moderate to severe irritable bowel syndrome under treatment

Protocol summary

Study aim

• Determining and comparing the average anxiety score in the group receiving TDCS and the control group, before and after the intervention and one month after the end of the intervention. • Determining and comparing the average score of depression in the group receiving TDCS and the control group, before and after the intervention and one month after the end of the intervention. • Determining and comparing the average score of the quality of life in the group receiving TDCS and the control group, before and after the intervention and one month after the end of the intervention. • Determining and comparing the mean score of symptom severity in the group receiving TDCS and the control group, before and after the intervention and one month after the end of the intervention.

Design

Clinical trial with two intervention and control groups, double blind and randomized on 40 patients. Statistical software is used for randomization

Settings and conduct

This study uses a double-blind (patient and evaluator) controlled randomized clinical trial. The study sample was selected from the patients referred to the psycho-physical clinic affiliated to Isfahan University of Medical Sciences in 1401.

Participants/Inclusion and exclusion criteria

Men and women aged 18 to 65 years; Diagnosis of moderate and severe IBS disorder based on ROME III criteria by gastroenterologist; Informed consent to participate in the study; Having at least reading and writing literacy; Living in the city of Isfahan

Intervention groups

This study examines the effect of direct electrical stimulation of the brain in patients with moderate and severe irritable bowel syndrome who are undergoing standard IBS treatment.

Main outcome variables

anxiety score; depression score; quality of life score; IBS symptom severity score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220727055566N1**
Registration date: **2022-12-20, 1401/09/29**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-20, 1401/09/29**
Update count: **0**

Registration date

2022-12-20, 1401/09/29

Registrant information

Name

Maedeh Rezaei Koujani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3421 5356

Email address

maedeh.rezaei48@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of trans cranial direct current stimulation (TDCS) intervention on improving anxiety, depression, quality of life, and severity of symptom in patients with moderate to severe irritable bowel syndrome under treatment

Public title

Investigating the effect of direct electrical stimulation of the brain in improving anxiety, depression, quality of life and severity of symptoms in patients with irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women aged 18 to 65 years Diagnosis of moderate and severe IBS disorder based on ROME III criteria by gastroenterologist Informed consent to participate in the study Having at least reading and writing literacy Living in the city of Isfahan

Exclusion criteria:

Diagnosing any organic disease during the study that makes it impossible to continue participating in the study. Failure to visit on time to complete the treatment process Intolerance of the patient to therapy Willingness to withdraw from the study for any reason The existence of serious suicidal thoughts or plans Pregnancy or breastfeeding Substance use History of seizures Having a pacemaker Taking antidepressants and anti-anxiety drugs from 2 weeks ago

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly selected and divided into intervention and control groups by Random Allocation Software. The randomization unit is individual. Randomization was done by statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

One group is treated with electrical stimulation of the brain and the other group is treated with sham TDCS as a control. In this way, the location of the electrodes is the same, with the difference that to feel the initial itching, the current is only applied for the first 30 seconds and then it is cut off during the test. The evaluator only had the patient's code and had no knowledge of control or intervention. The data analyst also had the data in two separate groups, but did not know which of the groups were intervention or control.

Placebo

Not used

Assignment

Parallel

Other design features

The people included in the study are randomly divided into intervention and control groups and we compare the effectiveness of the intervention before and immediately after and one month after the intervention between the two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

No. 15, Banafshe Miani Ave, Khane Esfahan Town

City

Esfahan

Province

Isfehan

Postal code

8194819474

Approval date

2020-10-18, 1399/07/27

Ethics committee reference number

IR.MUI.MED.REC.1399.637

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrome (IBS)

ICD-10 code

K58.3

ICD-10 code description

Irritable bowel syndrome with mixed bowel habits [IBS-M]

2

Description of health condition studied

Irritable Bowel Syndrome (IBS)

ICD-10 code
K58.1
ICD-10 code description
Irritable bowel syndrome with predominant diarrhoea [IBS-D]

3

Description of health condition studied
Irritable Bowel Syndrome (IBS)
ICD-10 code
K58.2
ICD-10 code description
Irritable bowel syndrome with predominant constipation [IBS-C]

Primary outcomes

1

Description
Depression score in Depression, Anxiety and Stress Scale questionnaire
Timepoint
Depression scores are measured before the start of the intervention, 5 days and 30 days after the start of the intervention.
Method of measurement
Depression, Anxiety and Stress Scale is a 21-question self-report questionnaire that is a set of 3 scales designed with 14 questions to measure negative emotional states in depression, anxiety and stress.

2

Description
Anxiety score in Depression, Anxiety and Stress Scale questionnaire
Timepoint
Anxiety scores are measured before the start of the intervention, 5 days and 30 days after the start of the intervention.
Method of measurement
Depression, Anxiety and Stress Scale is a 21-question self-report questionnaire that is a set of 3 scales designed with 14 questions to measure negative emotional states in depression, anxiety and stress.

3

Description
Stress score in Depression, Anxiety and Stress Scale questionnaire
Timepoint
Stress scores are measured before the start of the intervention, 5 days and 30 days after the start of the intervention.
Method of measurement
Depression, Anxiety and Stress Scale is a 21-question self-report questionnaire that is a set of 3 scales designed with 14 questions to measure negative emotional states in depression, anxiety and stress.

4

Description
Irritable bowel syndrome symptom severity score in irritable bowel severity scoring system questionnaire
Timepoint
The time periods of measuring the severity score of irritable bowel syndrome symptoms are done before the intervention, 5 days and 30 days after the intervention.
Method of measurement
The Irritable Bowel Severity Scoring System is a self-report questionnaire consisting of 5 sections that measures the severity of symptoms of irritable bowel syndrome, including pain, defecation disorder, bloating, the effect of the disease on daily life activities, and extraintestinal symptoms with a scale. Visual Analog Scale checks

5

Description
Score of quality of life in Irritable Bowel Syndrome - Quality of Life questionnaire
Timepoint
The time periods for measuring the quality of life score in irritable bowel syndrome disease are performed before the intervention, 5 days and 30 days after the intervention.
Method of measurement
The quality of life questionnaire for irritable bowel syndrome is a self-administered questionnaire with 34 questions that examines various aspects of the quality of life of people with irritable bowel syndrome.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group is treated with electrical stimulation of the brain. The anode of the device is placed at the F3 place on the skull and the cathode is placed at the F4 place on the skull. The number of these treatment sessions is 5 daily and with an intensity of 2 amps, each treatment session lasts 30 minutes.
Category
Treatment - Devices

2

Description
Control group: The control group of the TDCS device is placed on the skull. The anode of the device is placed at the F3 location on the skull and the cathode at the F4 location on the skull, and the current is applied only for the first 30 seconds, and then it is cut off during the test. The number of these sessions is considered to be 5 daily, each session lasting 30 minutes.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Azahra hospital of Esfahan, Psychosomatic clinic
Full name of responsible person
Fateme Sadat Naji
Street address
Soffe Blvd, Esfahan
City
Esfahan
Province
Isfehan
Postal code
8194819474
Phone
+98 31 3421 5356
Email
maedeh.rezaei48@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Asgari
Street address
Daneshgah Blvd, Azadi Square
City
Esfahan
Province
Isfehan
Postal code
8194819474
Phone
+98 31 3792 8092
Email
dean@med.mui.ac.ir
Web page address
https://med.mui.ac.ir/fa/pajoheshi
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Maedeh Rezaei Koujani
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No. 15, Vila Aley, Banafshe Miani Ave, Khane Esfahan Town
City
Esfahan
Province
Isfehan
Postal code
8194819474
Phone
+98 31 3421 5356
Email
maedeh.rezaei48@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Maedeh Rezaei Koujani
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No. 15, Vila Aley, Banafshe Miani Ave, Khane Esfahan Town
City
Esfahan
Province
Isfehan
Postal code
8194819474
Phone
+98 31 3421 5356
Email
maedeh.rezaei48@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Maedeh Rezaei Koujani

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
No. 15, Vila Ave., Banafsheh Miani Blvd., Khane Esfahan Town

City
Esfahan

Province
Isfehan

Postal code
8194819474

Phone
+98 31 3421 5356

Fax

Email
maedeh.rezaei48@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All study data will be shared after de-identification of study subjects.

When the data will become available and for how long
Access starts 6 months after results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
People who are looking to conduct scientific research can use the study data

From where data/document is obtainable
Maedeh Rezaei Koujani Tel:00989103044525 Email: Maedeh.Rezaei48@gmail.com

What processes are involved for a request to access data/document
One week after the request, the requested data will be provided

Comments