

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of The effect of transcranial direct current stimulation (tDCS) On anxiety at the night before elective surgery

#### Protocol summary

##### Study aim

Determination of the effect of transcranial direct current stimulation (tDCS) on preoperative anxiety

##### Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

##### Settings and conduct

This study is a double-blind, two-center randomized clinical trial that investigates the effect of tDCS on preoperative anxiety . According to the sample size and based on the inclusion criteria, 32 patients are admitted to the study. Using randomization method, half of the patients are in the case group and the other half are in the control group. A checklist is prepared for all patients, including social and demographic characteristics, substance abuse, previous surgical experience, knowledge of the disease, and knowledge of the type and reason for surgery. The night before the operation, the patients' anxiety level using the situational anxiety questionnaire The Spielberger Certificate (STAI) will be evaluated before and after the intervention.

##### Participants/Inclusion and exclusion criteria

All patients admitted to Imam Reza and Ghaem hospitals for elective cholecystectomy between the ages of 18 and 65, regardless of gender, who will be anesthetized if they meet the following conditions: Ability to read and write, Ability to speak and communicate, Right hand, no burns, lesions and tumors on the scalp, no history of brain tumors, no metal implants and pacemakers, no history of severe and recurrent headaches and head injuries,

##### Intervention groups

The night before the operation, the cathode electrode is placed on the right dorsolateral prefrontal cortex (DLPFC) in the case group and the anode electrode is placed on the left dorsolateral prefrontal cortex (DLPFC) with a current of 2 mA for 20 minutes.

##### Main outcome variables

Preoperative anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200823048494N1**

Registration date: **2021-01-17, 1399/10/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-01-17, 1399/10/28**

Update count: **0**

##### Registration date

2021-01-17, 1399/10/28

##### Registrant information

##### Name

Saeed Abedin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3608 6180

##### Email address

abedins961@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-25, 1399/10/05

##### Expected recruitment end date

2021-04-09, 1400/01/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of The effect of transcranial direct current stimulation (tDCS) On anxiety at the night before elective surgery

#### Public title

The effect of transcranial direct current stimulation on anxiety

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

ability to write and read ability to speak and communicate being right-handed

##### Exclusion criteria:

history of burn history of brain tumor history of pacemaker implantation or other devices history of severe headache or head trauma history of GAD, MDD, BMD , or schizophrenia

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **32**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

randomization is simple, using the randomized.com site and using a series of opaque and sealed envelopes.

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

Patients and researchers and data analyzer are blinded. after choosing the dim envelope by the patients. the envelope will be opened by health care assistants. transcranial direct current stimulation will be placed on the head of two groups of the patients, but in control group the device will turn on only for a few seconds.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

##### 1

##### Ethics committee

Name of ethics committee

Ethics committee of mashhad University of Medical Sciences

#### Street address

anesthesia department, Imam Reza hospital, mashhad

#### City

mashhad

#### Province

Razavi Khorasan

#### Postal code

9177899191

#### Approval date

2020-07-01, 1399/04/11

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.249

#### Health conditions studied

##### 1

##### Description of health condition studied

pre-operative anxiety

##### ICD-10 code

F06.4

##### ICD-10 code description

Anxiety disorder due to known physiological condition

#### Primary outcomes

##### 1

##### Description

pre-operative anxiety

##### Timepoint

night before surgery

##### Method of measurement

Spielberger Questionnaire

#### Secondary outcomes

empty

#### Intervention groups

##### 1

##### Description

Intervention group: The night before the operation, the cathode electrode is placed on the right dorsolateral prefrontal cortex (DLPFC) in the case group and the anode electrode is placed on the left dorsolateral prefrontal cortex (DLPFC) on the left with a current of 2 mA for 20 minutes.

##### Category

Prevention

##### 2

##### Description

Control group: The electrodes will be in the same arrangement for the duration and amount of the test group, except that the electric current is cut off after 30

seconds.

**Category**

Prevention

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Imam Reza hospital

**Full name of responsible person**

Mahdi Fathi

**Street address**

Imam reza square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177899191

**Phone**

+98 51 3802 2711

**Email**

fathim@mums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghoddi

**Street address**

Knowledge and Health City - In the end of Shahid  
Fakouri Blvd (In front of Fakouri 94) - Mashhad - Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91778-99191

**Phone**

+98 51 3884 9152

**Email**

tafaghodim@mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Saeed Abedin

**Position**

Anesthesia Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Reza hospital, Imam Reza square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91778-99191

**Phone**

00985138022711

**Email**

abedins961@mums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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۰۰۹۸۵۱۳۸۵۵۲۵۲۰۹

**Email**

abedins961@mums.ac.ir

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data can be published by deleting the personal details of the participants

**When the data will become available and for how long**

from 2022

**To whom data/document is available**

all the researchers

**Under which criteria data/document could be used**

for scientific researches only

**From where data/document is obtainable**

send request to correspond author fathim@mums.ac.ir

**What processes are involved for a request to access data/document**

send request via e-mail and explain why needs data

**Comments**