

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Investigating the effect of adding Transcranial direct current stimulation (TDCS) to acetaminophen codeine in reducing the pain of cancer patients in Isfahan city in 1401

#### Protocol summary

##### Study aim

1.Determination and comparison of the average pain score of the patients at the beginning, the first, second, third and fourth week after the intervention in the intervention group 2.Determining and comparing the average pain score of the patients at the beginning, the first, second, third and fourth week after the start of the intervention in the control group 3.Comparison of the average changes in the patients' pain scores in two groups

##### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3, on 30 patients, random allocation software was used for randomization

##### Settings and conduct

Cancer patients referring to Seyedal-Shohdai Hospital in Isfahan and Macsa Center (Iranian Cancer Control Center) will be included in the study. After dividing into two groups randomly, patients will get pain control using acetaminophen codeine in the control group or acetaminophen Codeine will be combined with TDCS (transcranial direct stimulation using two electrodes with a current of 2 mA for 20 minutes). In the control group, the electrodes will be placed on the patient's head, but no flow will pass. Due to the fact that all patients are conscious and the patient or health care provider is not informed about the intervention, study is double-blind

##### Participants/Inclusion and exclusion criteria

Patients with cancer between 18 and 65 years after obtaining written informed consent in the presence of pain and in the absence of any medical disorder, pregnancy or Narcotic addiction are included. In case of non-satisfaction at any stage, worsening of symptoms and need for hospitalization, or worsening of pain and need for other narcotics, the patient will be excluded

##### Intervention groups

1- The intervention group receiving acetaminophen

codeine with TDCS 2- Control group receiving acetaminophen codeine alone

##### Main outcome variables

Treatment with Tdcs; pain ;cancer stage

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220719055496N1**

Registration date: **2022-07-26, 1401/05/04**

Registration timing: **prospective**

Last update: **2022-07-26, 1401/05/04**

Update count: **0**

##### Registration date

2022-07-26, 1401/05/04

##### Registrant information

##### Name

Dorsa Davoodpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3786 2350

##### Email address

dorsa.davoodpour@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-06, 1401/05/15

##### Expected recruitment end date

2022-10-06, 1401/07/14

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of adding Transcranial direct current stimulation (TDCS) to acetaminophen codeine in reducing the pain of cancer patients in Isfahan city in 1401

**Public title**  
Investigating the effect of adding Transcranial direct current stimulation (TDCS) to acetaminophen codeine in reducing pain in cancer patients

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Any type of cancer Suffering from moderate to severe pain caused by cancer based on VAS score (5-10)  
Informed consent to participate in the study Absence of depressive disorders, bipolar disorders, or psychotic disorders based on DSM-V diagnostic criteria during examination by a psychiatrist and a psychiatric assistant  
No history of epilepsy and other neurological disorders  
Absence of pregnancy No addiction to drugs and opium  
Not having implants in the skull or pacemakers or any other prosthetics No prior exposure to transcranial stimulation treatments  
**Exclusion criteria:**  
The final stage of cancer Lack of informed consent  
Aggravation of cancer symptoms and the need for hospitalization during the study Intensification of pain in such a way that it is necessary to prescribe strong narcotics (morphine, methadone, oxycodone, pethidine)

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

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
After entering, patients will be divided into two groups by random allocation software in individual units by simple randomization method. After that, one of the groups will be randomly assigned to the intervention group and the other group to the control group

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The patients included in the study and the health care workers do not know the type of intervention performed

(TDCS or not) in the study

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Isfahan University of Medical Sciences  
**Street address**  
Isfahan university of Medical Science, Hezar Jarib St  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Approval date**  
2022-04-28, 1401/02/08  
**Ethics committee reference number**  
IR.MUI.MED.REC.1401.035

**Health conditions studied**

**1**

**Description of health condition studied**  
cancer related pain

**ICD-10 code**  
G89.3

**ICD-10 code description**  
Neoplasm related pain (acute) (chronic)

**Primary outcomes**

**1**

**Description**  
Pain score of cancer patients according to VAS (Visual Analog Scale)

**Timepoint**  
before the intervention and one week, two weeks, three weeks and four weeks after the intervention

**Method of measurement**  
The pain score of the patients is measured by the Visual Analog Scale ruler

**Secondary outcomes**  
empty

## Intervention groups

### 1

#### Description

Intervention group: The pain score of patients in this group is measured at the beginning of the study. Then the patients were treated for pain control with acetaminophen codeine along with Transcranial direct current stimulation (TDCS, with two electrodes that are placed on both sides of the head and then a current of 2 mA passes between them for 20 minutes) for 4 consecutive days in They are placed 4 separate times. After that, in the first week after the intervention, in the second, third and fourth week, the pain score of the patients is again measured by VAS (Visual Analog Scale) ruler

#### Category

Other

### 2

#### Description

Control group: The pain score of these patients is measured at the beginning of the study. Then the patients are treated with acetaminophen codeine alone for 4 consecutive days and for 4 separate times. Also, TDCS electrodes are placed on their heads, but no current passes through them. Then the pain of the patients is measured in the first week after the intervention, the second week, the third week and the fourth week by VAS (Visual Analog Scale) ruler

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Seyed-al Shohada Hospital

##### Full name of responsible person

Dorsa Davoodpour

##### Street address

Motahari St, Shahid Kharrazi Highway

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3235 0210

##### Email

Dorsa.davoodpour@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

macsa Institue

#### Full name of responsible person

Dorsa Davoodpour

#### Street address

No 29, 35th Alley, Motahari St, Shahid Kharrazi Highway

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#### Province

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8184933473

#### Phone

+98 31 3233 3029

#### Email

info@macsa.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dorsa Davoodpour

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Isfahan University of Medical Science, Hezar jarib St

##### City

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##### Province

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##### Postal code

8174673461

##### Phone

+98 31 3668 0048

##### Email

dean@med.mui.ac.ir

#### 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

Dorsa Davoodpour  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Psychiatrics  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
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Resident  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**

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## 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 data collected from patients can be shared after de-identification

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

Access starts for one year after the results are published

### To whom data/document is available

Doctors, researchers

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

The data will be used to conduct further studies in order to improve the condition of patients

### From where data/document is obtainable

Dr. Dorsa Davoodpour

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

After sending an email to receive data and verify identity, verify the person's job and the use of the data, the request will be reviewed and if approved, the data will be sent.

### Comments