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 clinicaltrial 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 between18 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

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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

Isfehan

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
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2

Recruitment center
Name of recruitment center
macsa Institue
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 updating data

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Fax
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Dorsa.davoodpour@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 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