

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of non-invasive transcranial direct current stimulation on pain and pain anxiety of burn dressing in Patients with burns

Protocol summary

Summary

The purpose of this randomized clinical trial is to investigate the effect of transcranial direct current stimulation on pain intensity and quality and pain anxiety of burn dressing change in hospitalized patients admitted to the Burn Center of the Emam Reza hospital in Mashhad. Sample: convenience sample of 60 patients, aged 15 to 60, TBSA %20-50, burn degree 2 or 3, able to speak and understand Persian, wound dressing by Dressing acid, povidone iodine. Sampling procedure: randomly assigned using stratification to either experimental or control groups. Pain intensity and quality and pain anxiety will be measured with Visual Analogue Scale (VAS) and the Short Form-McGill Pain Questionnaire and Burn Specific Pain Anxiety Scale (BSPAS) respectively. Scoring procedure: The scores of VAS range from 0-10, BSPAS range from 9-36 and Short Form-McGill Pain Questionnaire range from 0-41. The intervention consisted of 20 minutes of Cathodal somatic sensory cortex stimulation, with the current of 1 mA. While the control group will receive sham stimulation. Pain anxiety will be assessed before and after intervention and after dressing in experimental group. In control group it will be assessed before and after dressing. Pain quality will be also assessed just after dressing. Pain intensity will be assessed before and after dressing in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042817468N1**
Registration date: **2014-07-25, 1393/05/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-25, 1393/05/03

Registrant information

Name

Meysam Hoseini Amiri

Name of organization / entity

Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 0936

Email address

hoseiniam911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University Of Medical Sciences

Expected recruitment start date

2014-06-30, 1393/04/09

Expected recruitment end date

2014-10-01, 1393/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of non-invasive transcranial direct current stimulation on pain and pain anxiety of burn dressing in Patients with burns

Public title

The effect of transcranial direct current stimulation on pain and pain anxiety of burn in Patients with burns

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients in acute phase of burn injury, thermal burn, absence of face and neck burn, presence of psychological disorders currently or previously, the lack of complications related to neurological disorders leading to numbness in burned tissues, absence of severe visual and/or hearing problems, the absence of tumor and metallic implants in the head and upper back, the lack of brain trauma and epilepsy, absence of severe headaches. Exclusion criteria: Inability to do any stages of the procedure for any reason.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University Of Medical Sciences

Street address

Daneshgah street, Taghi abad, Mashhad

City

Mashhad

Postal code

Approval date

2015-02-08, 1393/11/19

Ethics committee reference number

921688

Health conditions studied

1

Description of health condition studied

Burns and corrosions

ICD-10 code

T29, T31

ICD-10 code description

Burns and corrosions of multiple body regions, Burns classified according to extent of body surface involved

Primary outcomes

1

Description

Intensity of burn dressing pain

Timepoint

Before and after intervention (before dressing) and After dressing

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Pain anxiety with burn dressing

Timepoint

Before and after intervention (before dressing) and after dressing in experimental group and also before and after dressing in control group

Method of measurement

Burn Specific Pain Anxiety Scale (BSPAS)

3

Description

Quality of burn dressing pain

Timepoint

After dressing

Method of measurement

The Short Form-McGill Pain Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

This group will receive catodal tDCS. Therefore the cathode electrode will be considered on the areas of right sensory cortex in the dorsal central position of right sulcus and anode electrode will be considered on the left prefrontal cortex, above the left eyebrow.

Category

Treatment - Other

2

Description

This group will receive sham tDCS so that device will turn off after 30 seconds of stimulation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

the Burn Center of the Emam Reza hospital in
Mashhad

Full name of responsible person**Street address**

Burn ward, Emam Reza Hospital, Taghi abad,
Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University Of Medical Sciences

Full name of responsible person

Mohamad Ramezani

Street address

Daneshga street, Taghi abad, Mashhad

City

Mashhad

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Mashhad University
of Medical Sciences

Full name of responsible person

Meysam Hoseini Amiri

Position

Masters Degree in Nursing (MSN)

Other areas of specialty/work**Street address**

Taghi Abad-Daneshgah st, Mashhad, Iran

City

Mashhad

Postal code

917794- 8988

Phone

+98 51 1859 8019

Fax

+98 51 1859 7313

Email

hoseiniam911@mums.ac.ir

hoseiniam987@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Mashhad University
of Medical Sciences

Full name of responsible person

Dr. SR. Mazloun

Position

PHD

Other areas of specialty/work**Street address**

Daneshgah St, Taghi Abad, Mashhad, Iran

City

Mashhad

Postal code

913791-3199

Phone

+98 51 1859 8019

Fax

+98 51 1859 7313

Email

mazlomr@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Mashhad University
of Medical Sciences

Full name of responsible person

Meysam Hoseini Amiri

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+98 51 1859 7313

Email

Hoseiniam911@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty