

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 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. Mazloum

**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

**Position**

Masters Degree in Nursing (MSN)

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

Daneshgah st, Taghi Abad, Mashhad, Iran

**City**

Mashhad

**Postal code**

917794-8988

**Phone**

+98 51 1859 8019

**Fax**

+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*