Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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
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917794- 8988
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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
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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
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Person responsible for updating data

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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