

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of accupressure on anxiety and pain of dressing in patient with burns.

Protocol summary

Study aim

Determine The effect of acupressure on anxiety and pain of dressing in patient with burns.

Design

Clinical trials with control and placebo group, Blind two-sided, Randomized.

Settings and conduct

This study was a double blind randomized trial with a sample size of 60 people, according to previous studies and 95% confidence level and 80% strength. The research environment of patients referred to the burn clinic of Imam Reza Hospital in Mashhad.

Participants/Inclusion and exclusion criteria

Inclusion criteria: alert and oriented; age between 18-60 years old; ability to read and write; to try to collaborate on the research; no cognitive and psychological disorders based on medical records; grade 2 burns, either superficial or deep, or both, with an area of less than 10%; no audicating and visual problems; no burns at the place of application of pressure points; no history of addiction or consumption of opioid analgesics; no history of sensory disorder in the burned limb. Exit criteria: the person's desire to continue cooperation at each stage of the study; patient's need for emergency medical intervention and the inability to use acupressure during intervention.

Intervention groups

For the intervention group, immediately before the dressing begins, an acupressure session is performed for 15 minutes by a nurse (researcher). First, the right (He gu) point then the same point in the left hand and at the end (Yin tang) each one for 5 minutes, is compressed continuously to the standard rate(3-4 kilograms). Patients in the placebo group also received no intervention. Only by placing the researcher next to them and just touching the acupressure points without pressure just before dressing.

Main outcome variables

Pain severity score; score of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180902040926N1**

Registration date: **2019-10-13, 1398/07/21**

Registration timing: **prospective**

Last update: **2019-12-22, 1398/10/01**

Update count: **1**

Registration date

2019-10-13, 1398/07/21

Registrant information

Name

amirhosein soltanpoor khazai

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-14, 1398/07/22

Expected recruitment end date

2019-11-06, 1398/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of accupressure on anxiety and pain of dressing in patient with burns.

Public title
The effect of accupressure on anxiety and pain of dressing in patient with burns.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Burn with Degree 2 in Surface or Deep Less than 10%
 Beware and Orient No cognitive and psychological disorder No drug addiction or drug use Non-burning pressure points at the acupressure location No history of sensory disorder in the limb with burns
Exclusion criteria:
 Unwillingness to continue research Emergency status (Such as respiratory distress, water and electrolyte disturbances) or pain intolerance and the need for emergency medical intervention to control pain

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
By simple randomization and classification method with the help of random number table.

Blinding (investigator's opinion)
Double blinded

Blinding description
The samples were divided into two intervention and placebo groups have no information about which group they are in. Researcher colleagues are unaware of the information gathered and the results of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah Ave.,

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2019-07-21, 1398/04/30

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.037

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Anxiety

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Burn

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score in the questionnaire VAS

Timepoint

Measure the severity of pain immediately before the intervention and during and after changing the dressing.

Method of measurement

Visual Analog Scale for pain Severity measurement (VAS)

2

Description

Anxiety Score in the questionnaire BSPAS.

Timepoint

Measure the amount of anxiety immediately before the intervention and after changing the dressing.

Method of measurement

Self-report questionnaire of Burn Specific Pain Anxiety Scale.

Secondary outcomes

1

Description

Score pain severity

Timepoint

Immediately before and after changing the dressing

Method of measurement

Visual Analog Scale for pain severity measurement (VAS)

2

Description

The rate of pain anxiety caused by burning dressing

Timepoint

Immediately before and after changing the dressing

Method of measurement

Burn Specific Pain Anxiety Scale (BSPAS).

Intervention groups

1

Description

Intervention group: In the intervention group, the nurse (researcher) performs the acupuncture for 15 minutes just before dressing up. First, the first (He gu) point of the right hand then the same point in the left hand and at the end point (Yin tang), Each one is compressed continuously for 5 minutes by researcher for 5 minutes to the standard rate (3-4 kilograms).

Category

Treatment - Other

2

Description

Control group: In the placebo (control) group patients, With the presence of a researcher near by patient, and just touch of acupuncture points without any pressure, (in order to remove the psychological effect of the presence of a researcher on the patient's bedside) patients change dressings.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Burning Clinic of Imam Reza Hospital in Mashhad

Full name of responsible person

Hamid Chamanzari

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Ebn-e-sina Ave.

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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Daneshgah ave., Ibn-e-sina ave.

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Web page address

<http://v-research.mums.ac.ir>

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

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

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Chamanzari

Position

Faculty member of School of Nursing and Midwifery of
Mashhad University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Amir Hosein Soltanpour Khazaei

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Student

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Other areas of specialty/work

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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

The whole potential data is published after being
unidentifiable

When the data will become available and for how long

Start the access period 6 months after printing the
results

To whom data/document is available

All interested persons

Under which criteria data/document could be used

Use will only be allowed with the source.

From where data/document is obtainable

Amir hosein soltanpour khazaei
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What processes are involved for a request to access data/document

Max 10 days after receiving email

Comments