Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 acupressure 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 tuch of accupressure points withot 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
Street address
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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Email
vcresearch @ mums.ac.ir
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 updating data

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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 soltanpourah931@mums.ac.ir +98 9154077916
What processes are involved for a request to access data/document
Max 10 days after receiving email
Comments