Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of acupressure on pain and vital signs after dressing in patients with burns

Protocol summary

Study aim
Effects of acupressure on pain and vital signs after dressing in patients with burns

Design
Blocked randomized, double blind, clinical trial study, single center, controlled placebo, sample size of 76 patients selected in 6 months; allocated to two groups through block randomization method.

Settings and conduct
The present study will be performed in a double-blind manner (one of the contributors performs the intervention plan and the other partner who does not know about the intervention will collect the data, the person analyzing the findings of the study will also be blind to this grouping) in Valiasr Hospital in Arak.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age15 to 55 years, burns degree of 2 or 3 with 15 to 65 percent burn level, stability of hemodynamic status Exclusion criteria: Burns on the head and face, Unwillingness to cooperate

Intervention groups
In the first day, the base line vital signs and pain of all samples will be checked in half an hour before entering into the dressing room. Then the samples of the intervention group receive acupressure in real points (third eye point (Yintang) and Shen men point)) and the samples of the control group receive acupressure in false points, and then will go to dressing room. The pain and vital signs of the patients will be checked again in minutes 15 and 30 after exiting of dressing room. On the second day, the intervention will be performed as mentioned above.

Main outcome variables
Pain, Blood pressure, pulse rate, Respiratory rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130424013110N12**
Registration date: **2020-12-27, 1399/10/07**
Registration timing: **prospective**

Last update: **2020-12-27, 1399/10/07**
Update count: **0**

Registration date
2020-12-27, 1399/10/07

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-04, 1399/10/15

Expected recruitment end date
2021-07-23, 1400/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of acupressure on pain and vital signs after dressing in patients with burns

Public title
The effect of acupressure in patients with burns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being at the age of 15 to 55 years old Burns degree of 2 or 3 with 15 to 65 percent burn level Stability of hemodynamic status
Exclusion criteria:
Burns on the head and face Unwillingness to cooperate
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study the randomization will be done using block randomization method. In order to allocate the patients randomly into Intervention and control groups, at first 19 blocks of size 4 with C and T letters (The letters indicate the intervention and control groups) are created. Then the blocks are randomly selected and arranged to obtain a sequential combination of 76 letters. Each letter will be placed in a sealed packet according to the obtained sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
One of the contributors performs the intervention plan and the other partner who does not know about the intervention will collect the data. Finally, after analyzing the questionnaires and entering them in SPSS-16, data analysis will be done. After analyzing data, the group code will be specified. Therefore, the person analyzing the findings of the study will also be blind to this grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij square
City
Arak
Province
Markazi
Postal code
38481-76941
Approval date
2020-09-20, 1399/06/30
Ethics committee reference number
IR.ARAKMU.REC.1399.211

Health conditions studied

1

Description of health condition studied
Burn
ICD-10 code
T31
ICD-10 code description
Burns classified according to extent of body surface involved

Primary outcomes

1

Description
Pain
Timepoint
30 min before and 15 and 30 minutes after leaving the dressing room
Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Systolic and diastolic blood pressure
Timepoint
30 min before and 15 and 30 minutes after leaving the dressing room
Method of measurement
manual measurement and digital blood pressure device

2

Description
Pulse rate
Timepoint
manual measurement and digital blood pressure device
Method of measurement
Radial Pulse

3

Description
Respiratory rate
Timepoint
manual measurement and digital blood pressure device
Method of measurement
Observation chest in a minute

Intervention groups

1

Description
Intervention group: in the first day, the base line vital signs and pain of patients will be controlled in half an hour before entering into the dressing room and patients in the experimental group receive acupressure in real areas (ying tang located between the eyebrows and the roots of the nose, shenmen located in the upper wall of the ear cavity on the non-dominant side) for 10 minutes and then will go to dressing room. The pain and vital signs of the patients will be controlled in minutes of 15 and 30 after exiting of dressing room. On the second day, the intervention will be performed as mentioned above.
Category
Treatment - Other

2

Description
Control group: in the first day, the base line of the vital signs and the pain of patients will be controlled in half an hour before entering into the dressing room and patients in the control group receive acupressure in false areas (the outer corner of the left eyebrow and the beginning of the non-dominant side ear cavity) for 10 minutes and then will go to dressing room. The pain and vital signs of the patients will be controlled in minutes of 15 and 30 after exiting of dressing room. On the second day, the intervention will be performed as mentioned above.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital Arak
Full name of responsible person
Mehdi Harorani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza Kamali
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Vice Chancellery For Research And Technology; University campus; Basij square
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3848176341
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Mehdi Harorani
Position
Academic Instructor
Latest degree
Master
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available