

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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: Age 15 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

Name

Mehdi Harorani

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

Street address

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University campus; Basij square

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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

Other areas of specialty/work

Nursery

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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