

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Aug 2026

The Effect of Acupressure on Anxiety and Sleep Quality in Patients with Burn

Protocol summary

Study aim

Effects of acupressure on Anxiety and Sleep Quality in Patients with Burn

Design

Blocked randomized, double blind, clinical trial study, single center, controlled placebo, sample size of 72 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 Anxiety and Sleep Quality of all samples will be checked. Then the samples of the intervention group for three consecutive days 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. On the fourth day Anxiety and Sleep Quality of the patients will be checked again

Main outcome variables

Anxiety: Sleep Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130424013110N13**

Registration date: **2021-03-19, 1399/12/29**

Registration timing: **prospective**

Last update: **2021-03-19, 1399/12/29**

Update count: **0**

Registration date

2021-03-19, 1399/12/29

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

2021-04-21, 1400/02/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Acupressure on Anxiety and Sleep Quality in Patients with Burn

Public title

The effect of acupressure in patients with burns

Purpose

Supportive

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 **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**

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 18 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 72 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

2021-03-03, 1399/12/13

Ethics committee reference number

IR.ARAKMU.REC.1399.338

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

Sleep Quality

Timepoint

Before and the fourth day of the intervention

Method of measurement

St. Mary's Hospital Sleep Questionnaire

2

Description

Anxiety

Timepoint

Before and the fourth day of the intervention

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first day, the base line Anxiety and Sleep Quality of all samples will be checked. Then the samples of the intervention group for three consecutive days receive acupressure in real points (third eye point (Yintang) and Shen men point)). On the fourth day Anxiety and Sleep Quality of the patients will be checked again

Category

Treatment - Other

2**Description**

Control group: In the first day, the base line Anxiety and Sleep Quality of all samples will be checked. Then the samples of the control group receive acupressure in false points. On the fourth day Anxiety and Sleep Quality of the patients will be checked again

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr Hospital Arak

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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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Person responsible for updating data

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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