Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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: 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 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
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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

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Province

Markazi

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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
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Sponsors / Funding sources

1

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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
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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