Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of foot reflexology on the severity of pain, anxiety and sleep quality in burns patients

Protocol summary

Study aim
The effect of foot reflexology on the severity of pain, anxiety and sleep quality in patients with burns

Design
In this study, 66 patients with burns with entry criteria are selected. Patients are randomly assigned to control and intervention groups using random numbers. Each group was assigned a code to hide the groups.

Settings and conduct
Department of Burning in Valiasr Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years Ability to speak No damage to the respiratory system Burns 45% -10% of the total body (TBSA) Burns Grade 2 and 3 Not Losing Sense of Pain Non-burning of the floor and on the legs Ability to communicate Log in three days after the accident (none of the participants in the acute phase enter the study) No addiction Lack of mental illness Lack of specific underlying disease (such as cancer, fracture, cuts and thyroid disease causing pain and anxiety) Exit criteria: Having problems with the legs, including problems with blood flow (confirmed by the cardiologist) No cuts, burns, fungal infections, varices and warts, corns and any type of numbness in the leg Use of other complementary and alternative methods during the study

Intervention groups
In the intervention group 3 times a week, one day in the middle for 30 minutes before the reflexology dressing will be done, the reflexology duration for each of the legs will be 15 minutes. Which will include 5 minutes of massage for the general foot and 10 minutes for massaging the solar system, pituitary and pineal gland. Controls: In the control group, they will receive routine care, and in addition, the intervener will carry out the on-patient intervention on the patient's leg 3 times a week in a day for 30 minutes before changing the gentle touching massage dressing, Duration for each leg is 15 minutes. This is due to the elimination of the effect of the interventional presence and the unification of interventions between the two groups.

Main outcome variables
Severity of pain; Anxiety; Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180103038211N1**
Registration date: **2018-02-13, 1396/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-13, 1396/11/24**
Update count: **0**

Registration date
2018-02-13, 1396/11/24

Registrant information

Name
Fahime Davodabady

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3226 7610

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-14, 1396/10/24

Expected recruitment end date
2018-05-20, 1397/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of foot reflexology on the severity of pain, anxiety and sleep quality in burns patients

Public title
The effect of reflexology on burn patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with grade 2 and 3 burns that burn 10 to 45% of their body surface.
Exclusion criteria:
There is a vascular, structural and burn problem in the legs.
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

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized random numbers were used for randomization in two groups of intervention and control.
Blinding (investigator's opinion)
Double blinded
Blinding description
Individuals with entry criteria are divided into two intervention and control groups according to the random numbers table. The people of the intervention group A and the control group B are called. Before and after the intervention, the information is collected by the evaluator of the outcome that is unaware of the grouping of the groups. Data analysis is also done by someone who is unaware of the allocation of groups.
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
Arak University of Medical Sciences, Basij Square, Sardasht
City
Arak
Province
Markazi
Postal code
6941-7-38481
Approval date
2017-12-17, 1396/09/26
Ethics committee reference number
IR.ARAKMU.REC.1396.232

Health conditions studied

1

Description of health condition studied
BURN
ICD-10 code
T20-T32
ICD-10 code description
Burns and corrosions

Primary outcomes

1

Description
Pain intensity in analgesic visual analog scale pain
Timepoint
One time before the intervention begins on the first day, 5-10 minutes before and after the dressing will be measured in both groups after the start of the intervention for 6 consecutive days.
Method of measurement
analgesic visual analog scale pain

2

Description
Anxiety level with visual analog scale Anxiety
Timepoint
One time before the intervention begins on the first day, 5-10 minutes before and after the dressing will be measured in both groups after the start of the intervention for 6 consecutive days.
Method of measurement
visual analog scale Anxiety

3

Description

Sleep quality with Pittsburgh questionnaire

Timepoint

At the beginning of the study and 6 days after the intervention began

Method of measurement

Pittsburgh questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group 3 times a week, one day in between 30 minutes before the reflexology dressing will be done, the reflexology time for each of the legs will be 15 minutes. Which will include 5 minutes of massage for the general foot and 10 minutes for massaging the solar system, pituitary and pineal .

Category

Treatment - Other

2

Description

Control group: In the control group, they will receive routine care and in addition, the intervener will carry out the treatment on the patient's leg 3 times a week in a day for 30 minutes before changing the soft touch massage dressing. , The duration for each of the legs will be 15 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Fahimeh Davodabady

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Arak University of Medical Sciences, Basij Square, Sardasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad arjomandzadegan

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Arak University of Medical Sciences, Basij Square, Sardasht

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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

Fahimeh Davodabady

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable