

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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)

Phone

+98 86 3226 7610

Email address

F_davodabady@arakmu.ac.ir

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

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

6941-7-38481

Phone

+98 86 3417 3503

Email

fahimedavodabady@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad arjomandzadegan

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

6941-7-38481

Phone

+98 86 3417 3503

Email

arjomandzadegan@arakmu.ac.ir

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

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

6941-7-38481

Phone

+98 86 3417 3503

Email

fahimedavodabady@gmail.com

Person responsible for scientific 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

Street address

Arak University of Medical Sciences, Basij Square,
Sardasht

City

Arak

Province

Markazi

Postal code

6941-7-38481

Phone

+98 86 3417 3503

Email

Fahimedavodabady@gmail.com

Person responsible for updating data

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

Street address

Arak University of Medical Sciences, Basij Square,
Sardasht

City

Arak

Province

Markazi

Postal code

6941-7-38481

Phone

+98 86 3417 3503

Email

fahimedavodabady@gmail.com

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