Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Foot reflexology on pain, fatigue, and sleep quality of patients undergoing renal transplantation surgery

Protocol summary

Study aim
To determine the effect of Foot reflexology on pain, fatigue, and sleep quality of patients undergoing renal transplantation surgery

Design
A randomized, parallel group clinical trial with a control group and without blinding

Settings and conduct
The study will be conducted on all patients with a kidney transplant in Afzalipour Hospital. The intervention will be done as a 30-minute massaging in three sessions. The pain, fatigue and sleep quality of patients will be measured before the intervention, immediately after the intervention and one week after the intervention

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients undergoing renal transplantation surgery, Being at least 15 years old, Having kidney transplant for the first time, Having no problems in feet, especially the sole; Exclusion Criteria: Having the experience of using foot reflexology

Intervention groups
Intervention group: In 3 sessions, the massaging protocol will be performed for 30 minutes on both feet, in 3 consecutive days. Control group: In the control group, no action will be taken.

Main outcome variables
Pain; Fatigue; Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170116031972N6**
Registration date: **2018-08-03, 1397/05/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-03, 1397/05/12**
Update count: **0**

Registration date
2018-08-03, 1397/05/12

Registrant information

Name
Mahlagha Dehghan Anari

Name of organization / entity
Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Foot reflexology on pain, fatigue, and sleep quality of patients undergoing renal transplantation surgery

Public title
The effect of foot reflexology on patients undergoing renal transplantation surgery

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being at least 15 years old Having kidney transplant for the first time Having no problems in feet, especially the sole Having full vigilance after the surgery No drug or alcohol addiction Patients undergoing renal transplantation surgery
Exclusion criteria:
Being blind or deaf Having the experience of using foot reflexology

Age
From **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be divided into the intervention and control group using the method of Minimization. Samples will be allocated to two groups according to gender variable and age (±2). In other words, the first sample is randomly assigned (using coin flipping or heads or tails) to one of the intervention or control groups, and the subsequent sample is allocated to the other group according to the matching variables (gender and age (±2)). If the subsequent sample would not match with the previous sample, it will be randomly assigned (using coin flipping or heads or tails) to one of the intervention or control groups using coin flipping or heads or tails. This process will continue until the sampling end so that at the end of the sampling, the two groups will be similar in age (±2) and gender.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences

Street address
Ebnesina St, Jahad Blvd, Somaye Crossroad, Kerman

City
Kerman

Province
Kerman

Postal code
7815789957

Approval date
2018-05-28, 1397/03/07

Ethics committee reference number
IR.KMU.REC.1397.071

Health conditions studied

1

Description of health condition studied
Patients' pain after renal transplantation surgery

ICD-10 code
R52.0

ICD-10 code description
Acute pain

2

Description of health condition studied
Patients' fatigue after renal transplantation surgery

ICD-10 code
R53

ICD-10 code description
Malaise and fatigue

3

Description of health condition studied
Patients' sleep quality after renal transplantation surgery

ICD-10 code
G47.9

ICD-10 code description
Sleep disorder, unspecified

4

Description of health condition studied
Kidney transplant

ICD-10 code
Z94.0

ICD-10 code description
Kidney transplant status

Primary outcomes

1

Description
Patient's pain score in Visual Analog Scale (VAS)

Timepoint
The first day after surgery, the second day after surgery before the intervention, immediately after the final session of intervention and one week after the final session of intervention

Method of measurement
Visual Analog Scale (VAS)

2

Description
Patient's fatigue score in Visual Analog Scale (VAS)
Timepoint
The first day after surgery, the second day after surgery before the intervention, immediately after the final session of intervention and one week after the final session of intervention
Method of measurement
Visual Analog Scale (VAS)

3

Description
Patient's sleep quality score in Pittsburgh Sleep Quality Index (PSQI)
Timepoint
The first day after surgery, the second day after surgery before the intervention, immediately after the final session of intervention and one week after the final session of intervention
Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Massaging intervention starts from the second day after the surgery. The massaging session starts in the final hours of the evening shift, at least 4 hours after the last time the sample received the last sedative. First, a quiet and bright environment will be prepared for the sample. Then massaging starts, first, the sole of the foot is gently massaged, gentle massage takes place in 3 minutes of the beginning and the final minutes of the intervention. The researcher takes the heel of one of the feet in his/her left hand and with the right-hand thumb applies pressure on the corresponding reflex points. The researcher, with his palm, pulls and pushes the outer edge of the foot forward and backward. For those samples who rarely go to the relaxation state, the solar plexus in the sole of the foot is also massaged to make the sample relax. Also, the parts related to the pineal gland are massaged in the outer part of the toe with slow speed and with regular rhythm or depth that is tolerable to the sample. The protocol is performed for 30 minutes on both feet (15 minutes each) for 3 sessions in 3 consecutive days.
Category
Rehabilitation

2

Description
Control group: In the control group, the researcher will do nothing and nurses will do caring procedures according to the protocol of the ward.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipoor Hospital
Full name of responsible person
Aliasghar Vahidi
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Afzalipoor Hospital, Imam Khomeini Highway, Kerman, Iran
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Web page address
http://www.kmu.ac.ir/fa/ah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
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vcr@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Atena Samareh fekri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Position

Faculty member

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Ph.D.

Other areas of specialty/work

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Latest degree

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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

There is 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

No - There is not a plan to make this available