Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of acupressure on severity of muscle cramp pain in hemodialysis patients

Protocol summary

Study aim

Determine the effect of acupressure on the severity of muscle cramp pain in hemodialysis patients

Design

Participants will be divided into two groups of test and control by simple random assignment.In this way, the first person chooses one from the two envelopes containing the group determination paper, identified by numbers 1 and 2,and the next person in the other group will give the participants the difference between the pressure not explained

Settings and conduct

In both groups, pressure is applied to the pressure points (real, unrealistic) separately and bilaterally for 5 minutes at each point and 15 minutes before dialysis and twice a week during dialysis and twice a week. Participants, carers, planners, and analysts are considered blind.

Participants/Inclusion and exclusion criteria

1 Willingness to participate in the study2.having an education 3.staying in the age range of 18 to 80 4.no drug addiction5. lack of anatomical and dermatological problems at the relevant points6. Not having a history of acupressure 7. No known underlying mental illness 8. Patients undergo cramps at least once a week9. Patients undergo dialysis at least twice a week.10. The patient has not participated in any other treatment for at least the last 2 weeks.

Intervention groups

In the test group, the intervention consisted of pressing on each of the points, SP6, LI4, LI 11 individually and bilaterally for 5 minutes at each point and 15 minutes before dialysis and during dialysis twice a week for two weeks.]n the control group (at the same rate and duration as the test group) at a 2 cm point in the main site, which is a false point, and It comes from acupuncture points.

Main outcome variables

Pain severity, muscle cramps

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190525043698N1**
Registration date: **2019-10-23, 1398/08/01**
Registration timing: **retrospective**

Last update: **2019-10-23, 1398/08/01**
Update count: **0**

Registration date

2019-10-23, 1398/08/01

Registrant information

Name

Amin Norozi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3757 6588

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aminnorozi051@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupressure on severity of muscle cramp pain in hemodialysis patients

Public title
The effect of acupressure on severity of muscle cramp pain in hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The willingness to participate in the study Having literacy Stay in the age range of 18 to 80 No addiction Not having anatomical and dermatological problems at the relevant points. Not having a history of using acupressure Missing mental illness detected Patients develop cramps at least once a week Patients undergo dialysis at least twice a week. The patient has not been involved in any other treatment for at least 2 weeks
Exclusion criteria:
Not wanting to continue studying for any reason Any problems or instability during the intervention Drug addiction Having a known mental illness
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be divided into two groups of experimental (acupressure) and control (pseudo-pressure) with simple random assignment using a sealed envelope. The first person then selects one of the two envelopes containing the group designation paper numbered 1 and 2, and then the next one falls into the other group to tell the participants about the difference between Pressure in the control and test groups is not explained. They were assured that there was no known complication for acupuncture and that they would be notified if any problems arose, and that they could be excluded if they did not wish to, and this would have an impact on their care. Will not leave.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants are blinded by the use of pressure on unrealistic points, statistical analysts by assigning code to questionnaires, designers by coding questionnaires, patient caregivers by applying pressure points to all patients
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ṡabzevar University of Medical Sciences
Street address
Deputy of Education,University Campus Building,Above the Unknown Martyrs' Tomb,Tohid Boulevard,Sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Approval date
2019-05-11, 1398/02/21
Ethics committee reference number
IR.MEDSAB.REC.1398.010

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
N03
ICD-10 code description
Chronic nephritic syndrome

Primary outcomes

1

Description
Pain severity: An unpleasant emotion and experience associated with actual or potential tissue damage.Practical Definition of Pain: A score obtained from a numerical pain scale
Timepoint
5 minutes before the intervention and then after the intervention
Method of measurement
visual Analogue Scale

2

Description
Muscle cramps: involuntary, sudden, prolonged, and usually painful contractions in one or more muscles, and may take from a few seconds to a quarter of an hour.
Timepoint

Before intervention start and end of intervention

Method of measurement

Patient self-report record

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention means pressing on each of the points, SP6, LI4, LI 11 individually and bilaterally for 5 minutes at each point and 15 minutes before dialysis and twice a week for two weeks and during dialysis. The correctness of the pressure is confirmed when the patient feels warm, heavy, swollen or numb at that point.

Category

Treatment - Other

2

Description

Control group: Pressure (equal to and equal to the test group) is applied at a 2 cm point in the main site, which is a false point and is not an acupressure point.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei Hospital of Sabzevar

Full name of responsible person

Alemeh Dehnabi

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Mohammad Vasiei Hospital,Tohid Shahr Boulevard, Sabzevar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshteh Ghorat

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Vice Chancellor for Research and Technolog,University of Medical Sciences Campus,Above Memorial of Unknown Martyrs, Boulevard of Nuclear Martyrs,Sabzevar

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Amin Norozi

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only part of the data, such as information about the main outcome or the like

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
For researchers working only in academic and scientific institutions

Under which criteria data/document could be used
For use in scientific articles

From where data/document is obtainable
aminnorozi aminnorozi051@gmail.com

What processes are involved for a request to access data/document
By email and send it

Comments