Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of acupressure on fear and stress amounts of emergency hemodialysis patients

Protocol summary

Study aim
Determining the effect of acupressure on the fear and stress of emergency hemodialysis patients
Design
A clinical trial, parallel intervention, control and sham groups, randomized based on random allocation 2 software, on 90 patients
Settings and conduct
Imam Khomeini Sari educational and therapeutic center
Participants/Inclusion and exclusion criteria
Age >18 years Candidate for emergency hemodialysis(HD) Mental alertness and absence of moderate and severe cognitive impairment based on MMSE At least 6 months history of HD Absence of limb amputation or wound at the place of pressure points A score of fear and stress ≥ 44 based on the VAS Not suffering from acute mental disorders or taking sedative drugs in last 2 weeks Not using acupuncture, hypnosis or Yoga for the past 6 months Not experiencing stressful events in the past 6 weeks No use of opium 5 hours before the start of HD؛ People's reluctance to participate in the study Need for CPR rebate the level of consciousness of patients during HD
Intervention groups
Acupressure group: 1hour after the start of hemodialysis, the first intervention will be performed by the therapist with measuring fear and stress. 2 hours after, the second round will be performed similar to the previous series. The fourth round of evaluation will be immediately before isolating the patients. In each round of intervention, points BL60, K3, GB20, SP6, K1 and Gv29 are massaged for 3 minutes(total:18 minutes) False group: intervention and measurement times will be similar to the acupressure group. The intervention will be done 2 cm away from the mentioned points, 1 and 2 hours after the start of hemodialysis. In these 2 groups, the amount of pressure will be 3 kg on the acupressure points. Control group: no intervention will be done for fear and stress, but the variables will be measured in the same order
Main outcome variables
fear ؛ stress

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20110906007494N45**
Registration date: **2024-05-16, 1403/02/27**
Registration timing: **prospective**

Last update: **2024-05-16, 1403/02/27**
Update count: **0**
Registration date
2024-05-16, 1403/02/27

Registrant information
Name
Masoumeh Bagheri Nesami
Name of organization / entity
Mazandaran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 11 3336 7551
Email address
mbagheri@mazums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-06-21, 1403/04/01
Expected recruitment end date
2024-12-20, 1403/09/30
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of acupressure on fear and stress amounts of emergency hemodialysis patients

Public title
The effect of acupressure on the fear and stress of dialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Emergency hemodialysis candidate based on nephrologist's diagnosis Mental alertness and absence of moderate and severe cognitive impairment based on Mini Mental State Examination A history of at least 6 months of hemodialysis Absence of limb amputation or wound at the place of pressure points Patients who have a score of 44 or higher based on the visual analog scale of fear Patients who have a score of 44 or higher based on the visual analog scale of stress Not suffering from acute mental disorders (panic attacks and anxiety disorders) and not taking sedatives such as benzodiazepines 2 weeks before the visit Not using accompanying treatment methods such as acupuncture, hypnosis or yoga during the last six months Not experiencing stressful events in the past six weeks No use of opium within five hours before the start of hemodialysis
Exclusion criteria:
Unwillingness to participate in the study The need for cardiopulmonary resuscitation following hemodynamic changes during hemodialysis Decreasing the level of consciousness of patients during hemodialysis
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, stratified random block method will be used. The randomization unit will be individual and in blocks of 3 people. To make a 3-person block, patients will be matched (classified) according to the gender variable. Next, in each block, patients will receive numbers 1 to 3 according to their arrival, and according to the A, B, C codes generated by the software, allocation will be done. Code A will be considered for the acupressure group, B for the sham intervention group, and C for the control group. The codes will be placed in the sealed envelope and the number of each patient will be written on the envelope.
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 Mazandaran University of Medical Sciences
Street address
Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square. , Sari, mazandaran, Iran.
City
Sari
Province
Mazandaran
Postal code
4816715793
Approval date
2024-04-17, 1403/01/29
Ethics committee reference number
IR.MAZUMS.REC.1403.012

Health conditions studied

1

Description of health condition studied
stress
ICD-10 code
F43.0
ICD-10 code description
Acute stress reaction

2

Description of health condition studied
fear
ICD-10 code
Z71.1
ICD-10 code description
Person with feared health complaint in whom no diagnosis is made

Primary outcomes

1

Description
stress
Timepoint
1 hour after connecting the patient to the hemodialysis machine and immediately after the first intervention (1hour after the start of hemodialysis), immediately after the second intervention (2 hours after the start of hemodialysis) and immediately before separating the patient from the hemodialysis machine
Method of measurement
A visual analog scale for measuring stress intensity with a 100 mm graduated ruler

2

Description
fear
Timepoint
1 hour after connecting the patient to the hemodialysis machine and immediately after the first intervention (1hour after the start of hemodialysis), immediately after the second intervention (2 hours after the start of hemodialysis) and immediately before separating the patient from the hemodialysis machine
Method of measurement
A visual analog scale for measuring fear intensity with a 100 mm graduated ruler

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: after introducing and stating the objectives of the study and obtaining written informed consent and getting the patient's cooperation to conduct the study in the first hour after the patient was connected to the hemodialysis machine, the demographic and medical information form including age, gender, occupation, marital status, Education level, place of residence, history of dialysis, underlying disease history, emergency cause of hemodialysis and vascular access ways, fear survey, stress survey and short mental status survey tool will be completed. Then, one hour after the start of hemodialysis, the first round of intervention will be performed by the therapist, and immediately after the first round of intervention, the fear and stress tool will be completed. Two hours after the start of hemodialysis, the second round of acupressure will be performed and the fear and stress of hemodialysis patients will be checked again. The fourth time will be to assess the fear and stress of the patients immediately before isolating the patients. In the acupressure group, at each round of intervention, pressure points BL60, K3, GB20, SP6, K1 and Gv29 are subjected to pressure massage by the researcher's fingers for three minutes each for a total of 18 minutes. The point BL60 (Kun Lun) next to the outer ankle of the foot is the end of the Achilles tendon. The K3 point (Taixi) is located in the middle of the distance between the inner ankle and the Achilles tendon. Point GB20 (Fengchi) is located between the base of the skull and the top of the neck, on the side of the tendons of the trapezius muscle. Point SP6 (Sanyinjiao) is located on the inner side of the lower leg and at a distance of three CUN above the inner part of the inner ankle of the leg, in the posterior line and next to the tibia bone on the spleen channel. K1 point (Yongquan) is the junction of the anterior third and posterior two thirds of the sole between the second and third toes. Point Gv29 (Yin Tang) is located in the middle between the two eyebrows
Category
Treatment - Other

2

Description
False intervention group: After introducing and stating the objectives of the study and obtaining written informed consent and getting the patient's cooperation to conduct the study, in the first hour after the patient is connected to the hemodialysis machine, the demographic and medical information form and the fear and stress assessment tool will be completed. Then, one hour after the start of hemodialysis, the first round of false intervention will be performed, and immediately after the first round of false intervention, the fear and stress tool will be completed. Two hours after the start of hemodialysis, the second round of false intervention will be performed and the fear and stress of hemodialysis patients will be checked again. The fourth time will be to assess the fear and stress of the patients immediately before isolating the patients. In this group, the intervention is two centimeters away from point K1 and GB20 to the right or left side, two centimeters away from point K3 and BL60 towards the ankle, two centimeters away from point SP6 towards the front of the foot and in the distance Two centimeters from the Gv29 point to the left or right side will be done one and two hours after the start of hemodialysis. points BL60, K3, GB20, SP6, K1 and Gv29 will be subjected to pressure massage by the researcher's fingers for three minutes each for a total of 18 minutes. In this group and the acupressure group, the amount of pressure of 3 kg will be determined in such a way that the researcher puts pressure on a scale with his thumb until the scale is fixed on the number 3 kg, and then with the same amount of pressure on It will put pressure on acupressure points.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person

Masoumeh Bagheri Nesami

Street address
School of Nursing and Midwifery Mazandaran University of Medical Sciences

City
Sari

Province
Mazandaran

Postal code
4816633131

Phone
+98 11 3336 1700

Fax
+98 11 3336 3754

Email
anna3043@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Masoumeh Bagheri Nesami

Street address
Moalem square , Moalem street

City
Sari

Province
Mazandaran

Postal code
4847193697

Phone
+98 11 3448 4848

Fax
+98 11 3448 4848

Email
mbagheri@mazums.ac.ir

Grant name
-Mazandaran University of Medical Sciences Research Assistant

Grant code / Reference number
-

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Masoumeh Bagheri Nesami

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Mazandaran University of Medical Sciences, Imam Square, Highway Bassij, 3-way Jouibar, Sari

City
Sari

Province
Mazandaran

Postal code
4816633131

Phone
+98 11 3336 7551

Fax
+98 11 1226 8915

Email
mbagheri@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Masoumeh Bagheri Nesami

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Mazandaran University of Medical Sciences, Imam Square, Highway Bassij, 3-way Jouibar, Sari

City
Sari

Province
Mazandaran

Postal code
4816633131

Phone
+98 11 3336 7551

Fax
+98 11 1226 8915

Email
mbagheri@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Masoumeh Bagheri Nesami
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Mazandaran University of Medical Sciences, Imam Square, Highway Bassij, 3-way Jouibar, Sari
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3336 7551
Fax
+98 11 1226 8915
Email
mbagheri@mazums.ac.ir

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