Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the effect of acupressure and clonazepam tablet on sleep quality of hemodialysis patients.

Protocol summary

Study aim
Determining the effect of acupressure and clonazepam tablet on sleep quality of hemodialysis patients

Design
Two-group randomized controlled clinical trial

Settings and conduct
In intervention group, acupressure in 6 points of the body will be pressed bilateral and simultaneous in the evening shift. Each point will be pressed for three minutes and the total intervention time will be 18 minutes. The intervention will be performed three times a week, one hour after the start of hemodialysis, for two weeks. The drug in the control group is clonazepam tablets, which will be given half a milligram of clonazepam tablets every night, half an hour before bedtime, for two weeks. The sleep quality with the PSQI index is completed before the start of the study and after two weeks. The place of study is the Shahrvand center of Sari city.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People 18 years and older with PSQI score(score 5 and above), hemodialysis two or three times a week, Iranian nationality, mental alertness, ability to answer questions, no delirium, no cognitive problems, no history of stroke and Incurable diseases, no severe hearing and vision problems and substance abuse, No amputation of limbs and wounds on acupressure points. Exclusion criteria: Patients taking anti-anxiety or hypnotic drugs, Patients using accompanying therapies such as acupuncture, herbal remedies, hypnosis or yoga .

Intervention groups
In the intervention group, acupressure 6 points of the body called PC 6-LI 4-KD1-SP 6-GB 20-HT 7 will be pressed bilateral and simultaneous in the evening shift. In the control group, clonazepam tablets will be given half a milligram of clonazepam tablets every night, half an hour before bedtime, for two weeks.

Main outcome variables
Sleep Quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110906007494N41**
Registration date: **2021-09-10, 1400/06/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-10, 1400/06/19**
Update count: **0**

Registration date
2021-09-10, 1400/06/19

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
2021-09-06, 1400/06/15

Expected recruitment end date
2021-10-07, 1400/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of acupressure and clonazepam tablet on sleep quality of hemodialysis patients.

Public title
The effect of acupressure and clonazepam tablet on sleep quality of hemodialysis patients.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People 18 years and older with Pittsburgh Sleep Quality Index(PSQI) score ≥ 5 Hemodialysis two or three times a week Iranian nationality Mental alertness and ability to answer questions Lack of delirium (Delirium Screening Nursing Scale (NE-DESC)) Lack Existence of cognitive problems (examination by Mini Mental State Examination (MMSE)) No history of stroke Lack of incurable diseases such as cancer Absence of severe hearing and vision problems No substance abuse No amputation of limbs and wounds on acupressure points

Exclusion criteria:
Patients taking anti-anxiety or hypnotic drugs due to neuropsychiatric disorders. Patients using combination therapies such as acupuncture, herbal remedies, hypnosis or yoga.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible individuals are randomly assigned to two groups of 30 intervention and control using random numbers provided by computer software and Permuted Block Randomization by a statistical consultant. 15 blocks of 4 so that in blocks of 4, two people from the intervention group and two people from the control group. Therefore, 60 envelopes are designed and the letter A (intervention group) and the letter B (control group) are embedded in it based on the information obtained from the computer program. Envelopes are numbered from one to 60. Respectively, the first patient who is admitted to the ward and has the inclusion criteria enters the study after obtaining informed written consent and sampling continues until patient number 60.

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
2021-06-13, 1400/03/23

Ethics committee reference number
IR.MAZUMS.REC.1400.233

Health conditions studied

1

Description of health condition studied
Sleep Quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sleep Quality

Timepoint
Before the intervention and after the intervention

Method of measurement
Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: acupressure 6 points of the body called HT.7 Shen Men, PC.6 Nei Guan, LI.4 Hegu, KD.1 Yong Quan, SP.6 Sanyinjiao, GB 20 Gallbladder 20, will

be pressed bilateral and simultaneous in the evening shift. Each point will be pressed for three minutes and the total intervention time will be 18 minutes. The intervention will be performed three times a week, one hour after the start of hemodialysis, for two weeks.

Category

Treatment - Drugs

2

Description

Control group: The drug in the control group is clonazepam tablets, which will be given half a milligram of clonazepam tablets every night, half an hour before bedtime, for two weeks to the subjects in the control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized clinic of Shahrvand Kidney Patients Center

Full name of responsible person

Mansooreh Ezzati

Street address

Juibar three ways, Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3336 1985

Email

mansoorehezati1994@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

Street address

Mazandaran university of Medical Sciences ,Valiye asr highway, Joybar 3way ,Imam Sq

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3397 8055

Email

mansoorehezaty1994@gmail.com

Grant name

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

PhD in Nursing Education

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

4816715793

Phone

7551 3336 11 98+

Fax

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

PhD in Nursing Education

Latest degree

Ph.D.

Other areas of specialty/work
Nursery
Street address
Mazandaran University of Medical Sciences, Three way Joibar, Highway basij, Imam square
City
Sari
Province
Mazandaran
Postal code
4816715793
Phone
+98 11 3379 5508
Email
Anna3043@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Masoumeh Bagheri Nesami
Position
PhD in Nursing Education
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nasibe Nursing and Midwiferi Faculty, Sari
City
Sari
Province
Mazandaran
Postal code
4816715793
Phone
+98 11 3379 5508
Email
Anna3043@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
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