

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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.

AgeFrom **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