# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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

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**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

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Majid Saeedi

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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**

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

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## Person responsible for updating data

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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