

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The effect of acupressure at P6 and Yiang point on anxiety, sleep quality, nausea and vomiting in hemodialysis patients

#### Protocol summary

##### Study aim

Comparison of the effect of acupressure in point of Yiang and P6 on anxiety, sleep quality ,nausea and vomiting in hemodialysis patients.

##### Design

This study includes three groups of point massage p6, yian and control group in parallel, double blind, the number of samples for each group is 12 people and the total sample is 36 people .we use Restricted randomization type of block randomization. In order to randomize the Random allocation software and pokets containing the intervention group are used and based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened and the assigned group of the participant is revealed.

##### Settings and conduct

The present study in the dialysis ward of Imam Ardabil Hospital is performed on dialysis patients. Patients and caregivers are unaware of how to perform massage on other groups.Because both methods are performed for all groups and the intervention method is done correctly and effectively and the other method is performed symbolically and incorrectly, patients and the caregiver are unaware of how to massage other groups.

##### Participants/Inclusion and exclusion criteria

Patient have a history of hemodialysis for at least six months, age group 18 to 65 years have inclusion criteria and patient with anxiety score less than 20, petersburg sleep standard less than 5 are exclusion criteria

##### Intervention groups

In the first group, acupressure is performed at point p6 of the inner part of the forearm as a massage with the index finger, and in the second group, acupressure at the Yiang point in the middle of the two eyebrows with massage of the thumb for 3-5 minutes, and in the third group at the false point. message is done three times a week for four weeks

##### Main outcome variables

Nausea and vomiting, anxiety, sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210403050823N2**

Registration date: **2021-07-28, 1400/05/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-07-28, 1400/05/06**

Update count: **0**

##### Registration date

2021-07-28, 1400/05/06

##### Registrant information

##### Name

solmaz saeidi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3242 6606

##### Email address

solmaz.saeidi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-26, 1400/05/04

##### Expected recruitment end date

2021-08-26, 1400/06/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of acupressure at P6 and Yiang point on anxiety, sleep quality, nausea and vomiting in hemodialysis patients

#### Public title

The effect of acupressure on anxiety, sleep quality, nausea and vomiting in hemodialysis patients

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Willingness to participate in the study Perform permanent hemodialysis Have a history of hemodialysis for at least six months Age group 18 to 65 years Ability to communication

##### Exclusion criteria:

Withdrawal from study Hospitalization of the patient during the intervention Amputation at the site of acupressure Anxiety score less than 20 Petersburg sleep standard less than 5

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Care provider
- Investigator

#### Sample size

Target sample size: **36**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

We will use method of Restricted randomization type of block randomization. Randomized tool is Random allocation software. We use the Allocation concealment method to hide that by using of pocket with Sequentially numbered, sealed, opaque envelopes Each of the random sequences created is recorded on a card and the cards are placed in the letter envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants into the study, one of the envelopes of the letter is opened and the assigned group of the participant is revealed.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The study participants and the people who do the intervention for the patients will be blind and think that the next groups will use this method as well. For all groups of patients in the same areas of acupressure, ineffective and symbolic massage is performed

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

##### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Khalkhal University of Medical Sciences

###### Street address

Mozaffar

###### City

Khalkhal

###### Province

Ardabil

###### Postal code

5681761351

##### Approval date

2021-07-11, 1400/04/20

##### Ethics committee reference number

IR.KHALUMS.REC.1400.005

#### Health conditions studied

##### 1

##### Description of health condition studied

Hemodialysis

##### ICD-10 code

R88.0

##### ICD-10 code description

Cloudy (hemodialysis) (peritoneal) dialysis effluent

#### Primary outcomes

##### 1

##### Description

Sleep quality score above 5

##### Timepoint

Quality of sleep before the intervention and four weeks after the intervention

##### Method of measurement

Petersburg Sleep Quality Questionnaire

#### Secondary outcomes

##### 1

##### Description

Anxiety score

##### Timepoint

Before intervention and four weeks after intervention

##### Method of measurement

Spielberger anxiety inventory

## Intervention groups

### 1

#### Description

Intervention group: Acupressure is performed in the first group on point P6, which is one of the points used to reduce patients' anxiety. This point is located between the inner forearm of the arm and in the cavity between the forearm bones about three inches wide and above the wrist crease.

#### Category

Prevention

### 2

#### Description

In the second intervention group, pressure is applied to the third eye area or yintang located between the eyebrows and the root of the nose.

#### Category

Prevention

### 3

#### Description

Control group: For the control group, the intervention is performed somewhere other than the main points and with the wrong massage, but at the same time

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ardebil University of Medical Sciences

##### Full name of responsible person

Esmaeel Mehraeen

##### Street address

Emam

##### City

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##### Province

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##### Postal code

5681761351

##### Phone

+98 45 3242 6606

##### Email

es.mehraeen@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Khalkhal University of Medical Sciences

##### Full name of responsible person

Emaeil Mehraeen

##### Street address

Mozaffar

##### City

Khalkhal

##### Province

Ardabil

##### Postal code

5681761351

##### Phone

+98 45 3242 6606

##### Email

es.mehraeen@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Khalkhal 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

Khalkhal Yuniversity of Medical Sciences

##### Full name of responsible person

Solmaz Saeidi

##### Position

Instructor

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Person responsible for updating data****Contact****Name of organization / entity**

Khalkhal University of Medical Sciences

**Full name of responsible person**

Solmaz Saeidi

**Position**

Instructor

**Latest degree**

Master