

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison slow stroke back massage and acupressure effect on skin pruritus in hemodialysis patients

Protocol summary

Study aim

Comparison of the effect of slow stroke back massage and acupressure on skin itching in hemodialysis patients

Design

Randomized clinical trial with two intervention parallel groups, without blinding, on 54 patients. Random Allocation software site will be used for randomization.

Settings and conduct

The hemodialysis ward of Mehr and 17 Shahrivar hospitals in Mashhad has been selected as the sampling location. 54 patients with pruritus are admitted to the study with satisfaction and will be placed in the group of massage or acupressure based on random allocation. For each group, the necessary forms and questionnaires will be completed at specified intervals and interventions will be performed for 12 sessions of 5-10 minutes after hemodialysis.

Participants/Inclusion and exclusion criteria

willingness to participate in the study, visual, auditory and alert ability to answer questions, undergoing hemodialysis for at least 6 months, referring to hemodialysis 3 sessions 3 to 4 hours a week, no liver disease, No amputation in the lower and upper limbs, mild to severe itching based on the visual scale of itching and a score between 1 and 10 at least 2 weeks before the test, no itchy skin lesions, body temperature between 36.5 to 37.5 ° C , No open wound or infection in the intervention area, dialysis solution temperature between 36.5 to 37.5 ° C, no use of traditional medicine to relieve itching 1 week before the test and age between 18 to 80 years

Intervention groups

Group A: Perform 12 sessions of slow stroke massage from the neck to the sacral area, 3 sessions per week and 10 minutes per session Group B: Perform 12 sessions of acupressure in points LI 11 and SP 10, 3 sessions per week and each session for 5 minutes at each point

Main outcome variables

Itching of the skin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200727048223N1**

Registration date: **2020-09-29, 1399/07/08**

Registration timing: **prospective**

Last update: **2020-09-29, 1399/07/08**

Update count: **0**

Registration date

2020-09-29, 1399/07/08

Registrant information

Name

Sina Salati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

salatis982@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The comparison slow stroke back massage and acupressure effect on skin pruritus in hemodialysis patients

Public title
The effect of massage and acupressure on skin itching

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Acceptable visual, auditory and consciousness ability to answer questions Undergoing hemodialysis for at least 6 months Referring to hemodialysis 3 sessions 4 hours a week The presence of mild to severe skin itching based on the visual scale of itching and a score between 1 to 10 at least 2 weeks before the test Dialysis solution temperature between 36.5 to 37.5 ° C Age between 18 to 80 years
Exclusion criteria:
liver diseases Amputation in the lower and upper limbs Existence of any itchy skin lesions Existence of open wound or infection in the intervention area Use traditional medicine to relieve itching 1 week before the test Body temperature above 37.8 ° C

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the permutation block method was used to generate a sequence of random allocation of samples(by individual) to the study groups. Random allocation sequences were performed using randomization software and block size two. The permutation block method is one of the random allocation methods in which each block is selected according to the number of groups studied. In this study, there are two blocks, AB and BA. One of the blocks is selected at random. If the first block, AB, is selected, the first person is assigned to group A and the second person to group B. And this process continues until all the samples are assigned. The characteristic of this method is that the two study groups will have equal numbers.

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 Mashhad University of Medical Sciences

Street address

Daneshgah Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2020-07-12, 1399/04/22

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.030

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

2

Description of health condition studied

skin pruritus

ICD-10 code

L29.9

ICD-10 code description

Pruritus, unspecified

Primary outcomes

1

Description

Itching of the skin

Timepoint

Measurement of skin itching at the beginning of the study, weekly and at the end of the study after massage and acupressure interventions

Method of measurement

Yosipovitch Itching Questionnaire

Secondary outcomes

1

Description

The effect of itchy skin on daily activities

Timepoint

At the beginning of the study, 7 days, 14 days, 21 days and 28 days after the start of massage and acupressure

Method of measurement

Yosipovitch pruritus questionnaire

2

Description

Effect of skin itching on sleep

Timepoint

At the beginning of the study, 7 days, 14 days, 21 days and 28 days after the start of massage and acupressure

Method of measurement

Yosipovitch pruritus questionnaire

3

Description

Effect of skin itching on quality of life

Timepoint

At the beginning of the study, 7 days, 14 days, 21 days and 28 days after the start of massage and acupressure

Method of measurement

Yosipovitch pruritus questionnaire

4

Description

Emotional skin itching dimension

Timepoint

At the beginning of the study, 7 days, 14 days, 21 days and 28 days after the start of massage and acupressure

Method of measurement

Yosipovitch pruritus questionnaire

5

Description

Skin itching severity

Timepoint

At the beginning of the study, 7 days, 14 days, 21 days and 28 days after the start of massage and acupressure

Method of measurement

Yosipovitch pruritus questionnaire

6

Description

Location of itching

Timepoint

At the beginning of the study, 7 days, 14 days, 21 days and 28 days after the start of massage and acupressure

Method of measurement

Yosipovitch pruritus questionnaire

Intervention groups

1

Description

Intervention group: Perform 12 sessions of slow stroke massage from the neck to the sacral area, 3 sessions per week and 10 minutes per session

Category

Treatment - Other

2

Description

Intervention group: Perform 12 sessions of acupressure in points (LI 11 at the outer end of the cubital) and (SP 10 in the area above the upper corner of the patella of the knee) 3 sessions per week and each session for 5 minutes at each point

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr hospital

Full name of responsible person

Qolam-reza Faroudi

Street address

Mehr hospital, Alandasht sqr, Kouhsangi Avenue, Mashhad, Razavi Khorasan Province

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pr@mehrhospital.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaqodi

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Tayebe Pourghaznein

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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

Mashhad University of Medical Sciences

Full name of responsible person

Sina Salati

Position

Msc student

Latest degree

Bachelor

Other areas of specialty/work

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

In this study, all participants' data (demographic

information, laboratory indicators and questionnaire scores) will be available after being identified.

When the data will become available and for how long

Access period starts 3 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Academic researchers will be able to submit requests for data, and all quantitative and qualitative inferential and analytical analyzes of the data will be allowed.

From where data/document is obtainable

Sina salati . salatis982@mums.ac.ir Tayebe

Pourghaznein. PourghazneinT@mums.ac.ir

What processes are involved for a request to access data/document

The applicant must write a formal application to the corresponding author, announcing his application. After approval and coordination with the Vice Chancellor for Research, the study data will be sent to the applicant formally and confidentially.

Comments