

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Randomised Clinical Trial of Effect of acupressure of points SP6,SP10,ST36,LI-11 on uremic pruritus, quality of life, and laboratory parameters in hemodialysis patients

Protocol summary

Summary

The aim of this study is to investigate the efficacy of acupressure therapy on uremic pruritus, quality of life, and laboratory parameters of patients with hemodialysis. The study population consists of all the subjects who were undergoing hemodialysis in three educational hospitals. Subjects who are on dialysis for at least 6 months and they have experienced itching at least for 3 months will be included and who have history of non uremic itching, liver disease, cancer, psychiatric disorder and current infection will be excluded from study. The sample size is 90 patients that will be recruited in three groups by block randomization method. In this clinical trial the baseline measurements include itching severity scale, quality of life questionnaire, and laboratory tests. The intervention will be done during four weeks. In the first intervention group a one-minute pressure [4 (kg)] and consequently three consecutive pressures will be applied by researcher's thumb on SP6, SP10, ST36, LI-11 points. In second intervention group, pressure will be applied 1-2 centimeter far from mentioned points with similar technique and duration. The control group did not receive any intervention expect general therapies. Post-test will be performed within one week after completion of the intervention. Severity of pruritus was measured at the end of second week of intervention. Data will be collected using 5-D pruritus questionnaire, and quality of life questionnaire (Itching QoI) for itching.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041917546N8**

Registration date: **2017-07-05, 1396/04/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-05, 1396/04/14

Registrant information

Name

Marzieh Momennasab

Name of organization / entity

Shiraz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-06-16, 1396/03/26

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomised Clinical Trial of Effect of acupressure of points SP6,SP10,ST36,LI-11 on uremic pruritus, quality of life, and laboratory parameters in hemodialysis patients

Public title

Effect of acupuncture on severity of pruritus, quality of life, and laboratory parameters in hemodialysis patients

IR.SUMS.REC.1395.198

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients Must be on dialysis for at least 6 months; Their age should be in range of 18 to 65 years; Having itching at least for 3 months; Must be on dialysis at least three times a week for 3-4 hours; Should have intact sense in acupuncture points. Exclusion criteria: The patient declines to cooperate; There is wound at acupuncture points; Suffering from viral hepatitis or AIDS, Being hospitalized in the last month; Having any surgery; amputation or neuropathy in the last three months; Having history of non uremic itching, liver disease, cancer, psychiatric disorder and current infection.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study randomization will be done by blocking method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand Av, The Central Building of Shiraz University of Medical Sciences, Shiraz, Iran

City

Shiraz

Postal code

Approval date

2017-03-13, 1395/12/23

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

Extracorporeal dialysis

Primary outcomes

1

Description

Uremic pruritus

Timepoint

Before. The end of the second week and the end of the fifth week after beginning the intervention

Method of measurement

5-D Pruritus Scale

2

Description

Quality of Life

Timepoint

Before and the end of fifth week after beginning the intervention

Method of measurement

Quality of Life Questionnaire in patients with pruritus (Itchy QoL)

3

Description

Biochemical parameters including hemoglobin, hematocrit, phosphorus, calcium, sodium, potassium, PTH, BUN, and Cr

Timepoint

Before and the end of fifth week after beginning the intervention

Method of measurement

Blood sample

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group 1: In this group intervention will be done three times a week during dialysis. A one-minute pressure amount of 4 (kg) will be applied on SP6, SP10, ST36, LI-11 points by the research using thumb. Also, three consecutive pressures were applied in each point.

Category

Other

2

Description

Intervention group2: In this intervention group, pressure will be applied in sham-control points that are 1-2 centimeter far from major points with similar technique and duration.

Category

Other

3

Description

control group: Without intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi Hospital

Full name of responsible person

Fateme Karjalian

Street address

Next to Medical School, Zand Avenue, Shiraz, Iran

City

Shiraz

2

Recruitment center

Name of recruitment center

Amiralmomenin brun hospital

Full name of responsible person

Fateme Karjalian

Street address

Km 2 Sadra, Amiralmomenin burn and plastic hospital

City

Sadra

3

Recruitment center

Name of recruitment center

Nemazee hospital

Full name of responsible person

Fateme Karjalian

Street address

Namazee square, Zand Avenue, Shahid Faghihi

Hospital, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

7th floor, central building of Shiraz University of Medical Science, Zand boulevard

City

Shiraz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for Research of Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hazrate Fateme nursing and midwifery school

Full name of responsible person

Dr. Marzieh Momennasab

Position

assistant professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty