Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Acupuncture ,as a complementary medicine,in controlling pruritus in hemodialysis patients

Protocol summary

Summary

In this study, a randomized clinical trial, samples are selected among dialysis patients in hospitals affiliated to Mashhad University of Medical Sciences.They are older than 18 and younger than 65 years old with pruritus for more than three months despite routine treatment .These patient are under dialysis for at least 6 months, Visual Analogue Scale questionnaire Score more than 4 and are able to answer the questions.After completing the questionnaires by the investigator and consent form by patient, dermatologist does skin punch biopsy in the dorsal surface of the hand and prescribes Gabapentin(200-300 mg daily) for every patient and refers them to acupuncture clinic . Patients were randomly located in one of the 2 groups by acupuncturist. Intervention group receive acupuncture treatment by needling in the SP10, st36, LI4, LV3, sp6 ,2 times a week, for 6 weeks .control group receive sham acupuncture treatment by needling at 1 cm outside the corresponding acupuncture point with similar duration and frequency. After the last session of intervention, patient are referred to dermatology clinic and biopsy on the same condition is prepared and will be sent pathology lab to compare the mast cell infiltration with first biopsy. Before and after treatment, VAS and quality of life questionnaire will be completed by investigator and the mast cell infiltration will be compare by pathologist in both groups then data will be analyzed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062720282N2**
Registration date: **2017-03-28, 1396/01/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-28, 1396/01/08

Registrant information

Name
Shapour Badiee Aval
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 3843 6829
Email address
badieeash@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-03-30, 1396/01/10

Expected recruitment end date

2017-05-15, 1396/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Acupuncture ,as a complementary medicine,in controlling pruritus in hemodialysis patients

Public title

The Effect of Acupuncture on hemodialysis pruritus

Purpose

Treatment

Inclusion/Exclusion criteria

Main Inclusion criteria are:hemodialysis patients; older

than 18 years and less than 65 years old; Itching for more than 3 months despite recieving conventional therapy ;VAS scale score greater than 4;Under Hemodialysis at least 6 months ;Be able to answer the questions. Main Exclusion criteria are: Age less than 65 years or more than 18 years; history of bleeding or coagulation disorders;any history of skin disease,psychiatric disease,cancer,liver disease.;.No willing to continue acupuncture treatment during study

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Daneshgah 16

City
Mashhad

Postal code

Approval date
2015-07-22, 1394/04/31

Ethics committee reference number
IR.MUMS.FM.REC.1394.223

Health conditions studied

1

Description of health condition studied
Renal failure under Hemodialysis

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
pruritus

Timepoint
before and after intervention

Method of measurement
VAS questionnaire

Secondary outcomes

1

Description
Mast cell infiltration

Timepoint
Before and after intervention

Method of measurement
The number of mast cells per microscopic magnification 40 after Giemsa stain

2

Description
Quality of life

Timepoint
Before and after

Method of measurement
Quality life questionnaire

Intervention groups

1

Description
Control Group: Based on inclusion and exclusion criteria,patients are selected.They fill consent and questionnaires forms then dermatologist does skin punch biopsy in the dorsal surface of the hand and prescribes Gabapentin(200-300 mg daily) for Every patient and refers them to acupuncture clinic . Patients are located randomly in one of the 2 groups by acupuncturist through the draw of the parcel.Control group receive acupuncture by needling at 1 centimeter outside certain acupuncture point similar to intervention group, by expert, 2 times a week, for 6 weeks. After the last session of acupuncture, patients fill questionnaires again and are referred to dermatology clinic.Biopsy on the same condition is prepared and sent to pathology lab to compare the mast cell infiltration with first biopsy.

Category
Treatment - Other

2

Description
Intervention group: Based on inclusion and exclusion criteria,patients are selected.They fill consent and

questionnaires forms then dermatologist does skin punch biopsy in the dorsal surface of the hand and prescribes Gabapentin(200-300 mg daily) for Every patient and refers them to acupuncture clinic . Patients are located randomly in one of the 2 groups by acupuncturist through the draw of the parcel. Intervention group receive acupuncture treatment by needling in the SP10, ST36, LI4, LV3, SP6 by experts 2 times a week, for 6 weeks .After the last session of acupuncture, patients fill questionnaires again and are referred to dermatology clinic.Biopsy on the same condition is prepared and sent to pathology lab to compare the mast cell infiltration with first biopsy.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis Department of Hospitals affiliated to Mashhad University of Medical Sciences

Full name of responsible person

Shapour Badiee Aval

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tafaghodi Mohsen

Street address

Daneshgah Street,Daneshgah 16,Central Building of University,Ghoreshi

City

Mashhad

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

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

Mashhad University of Medical Sciences

Full name of responsible person

Shapour Badiee Aval

Position

Assistant Professor

Other areas of specialty/work

Street address

School of Persian and Complementary Medicine

City

Mashhad

Postal code

Phone

+98 51 3768 8519

Fax

Email

Badieeash@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

ShapourBadiee Aval

Position

Assistant Professor

Other areas of specialty/work

Street address

School of Persian and Complementary Medicine

City

Mashhad

Postal code

Phone

+98 51 3768 8519

Fax

Email

Badieeash@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Shapour Badiee Aval

Position

Assistant Professor

Other areas of specialty/work

Street address

Daneshgah 16

City

Mashhad

Postal code

Phone

+98 51 3768 8519

Fax

Email

Badieeash@mums.ac.ir

Web page address

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