

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Checking the effect of acupuncture on muscle cramp in dialysis patient

Protocol summary

Study aim

Checking the effect of acupuncture on muscle cramp in dialysis patients

Design

This study is a single-blind clinical trial. Based on this, 60 patients are selected and severity and frequency of muscle cramps are randomly divided into two groups. Drugs used. 15 minutes before hemodialysis, the control group is operated. Interventions in the case group are in acupuncture.

Settings and conduct

The study starts by collecting patients in dialysis ward of nemazee and faghihi Shiraz and acupuncture in physiotherapy and rehabilitation clinics by medical students and relevant rehabilitation specialist professors after getting the testimonial will continue

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients with chronic renal failure who were treated with hemodialysis; History of cramp have frequent muscle; at the time of sampling on the list are not linked; Infectious diseases, acute articular rheumatism, skin diseases, wounds, open fractures, deep vein thrombosis, Burns, and arm or leg amputation is not; particular anticoagulant drugs such as vitamin E and the pain is not used

Intervention groups

Intervention group: Acupuncture plus routine medical treatment of pre-existing muscle cramps Control group: Routine medical treatment of muscle cramps according to physician's prescription

Main outcome variables

muscle cramps during or after dialysis- consumer medication side effects

General information

Reason for update

Modification of recruitment date

Acronym

IRCT registration information

IRCT registration number: **IRCT20181121041716N1**

Registration date: **2019-12-16, 1398/09/25**

Registration timing: **prospective**

Last update: **2023-06-06, 1402/03/16**

Update count: **1**

Registration date

2019-12-16, 1398/09/25

Registrant information

Name

Maryam Vejdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3724 2718

Email address

vejdani_m@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-15, 1398/10/25

Expected recruitment end date

2020-07-31, 1399/05/10

Actual recruitment start date

2020-01-15, 1398/10/25

Actual recruitment end date

2020-07-31, 1399/05/10

Trial completion date

2020-07-31, 1399/05/10

Scientific title

Checking the effect of acupuncture on muscle cramp in dialysis patient

Public title

Acupuncture in dialysis patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic renal failure who were treated with hemodialysis; History of frequent muscle cramp; At least 6 months last from the time start dialysis; Not have been in the transplant list at the time of sampling Three times a week became dialysis with bicarbonates and each time lasts for 4 hours

Exclusion criteria:

Infectious dx Anticoagulant agent Pt with active Radiculopathy Skin dx Rhomatoid Arteritis Vit E Analgesic drugs Lumbosacral Discopathy Spinal canal stenosis Symptomatic Lumbosacral Peripheral Neuropathy Restless leg syndrome Iron deficiency anemia (ferritin less than 50)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization Statistical software randomization Individual random unit

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants put needle on the foot of the patients who have not received the medication that we're pretending to do acupuncture

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz Univercity of Medical Sciences

Street address

Setad Ave

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2019-01-23, 1397/11/03

Ethics committee reference number

IR.SUMS.MED.REC.1397.480

Health conditions studied

1

Description of health condition studied

Mucsl cramp in dialysis peitient

ICD-10 code

M62.00

ICD-10 code description

Separation of muscle (nontraumatic), unspecified site

Primary outcomes

1

Description

1) cramp frequency

Timepoint

before and after acupancture and one mounth after finishing procidure

Method of measurement

questioner of amounth of number of muscle cramp

2

Description

cramp severity

Timepoint

before and after acupancture and one mounth after finishing procidure

Method of measurement

questioner of amounth of number of muscle cramp

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acupuncture plus routine medical treatment of pre-existing muscle cramps

Category

Treatment - Other

2

Description

Control group: Routine medical treatment of muscle cramps according to physician's prescription

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital-Faghihi hospital

Full name of responsible person

Dr Alireza Dabaghmanesh

Street address

Namazi Squer

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Dr Ahmad Bazoojoo

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Medravabet@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Fasa 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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Vejdnpak

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

Rehabilitation

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sharareh Roshanzamir

Position

Professor of Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

Others

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Based on editor opinion

When the data will become available and for how long

Based on editor opinion

To whom data/document is available

Based on editor opinion

Under which criteria data/document could be used

Based on editor opinion

From where data/document is obtainable

Based on editor opinion

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

Based on editor opinion

Comments