Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Cheking the effect of acupancture on muscle cramp in dialysis patient

Protocol summary

Study aim
Cheking the effect of acupancture on muscle cramp in dislysis 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 Vejdanpak

Name of organization / entity

Country
Iran (Islamic Republic of)

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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
Cheking the effect of acupancture on muscle cramp in dialysis patient

Public title
Acupancture in dyalisis paitient

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 sampeling Three times a week became dialysis with bicarbonates and each time lasts for 4 hours

Exclusion criteria:

Infectious dx Anticoagulant agent Pt with active Radicolopathy 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

Mucsle 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
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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
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 Vejdanpak
Position
Medical Student
Latest degree
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Person responsible for updating data

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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