Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of progressive muscle relaxation on pruritus severity of hemodialysis patients

Protocol summary

Summary

Pruritus is a common and disabling symptom experienced by end stage renal disease patients. Based on, present research is conducted to determine the effect of progressive muscle relaxation on pruritus of hemodialysis patients. This research is a randomized controlled clinical trial. Researcher refers to hemodialysis center of Modares hospital of Saveh and introduces the goal of research to patients, 60 patients with pruritus were selected with purposive sampling method and informed written consent was received. Data is collected by demographic data questionnaire, pruritus scale and visual analogue scale for determining of pruritus severity. Samples are randomizing allocated to intervention and control group and the questionnaires were completed by them. Researcher trains the progressive muscle relaxation method to intervention group. The training of PMR is done with one to one, face to face and practical method; also, instruction pamphlet and a compact disk of relaxation method are given to intervention group samples. After one month, pruritus severity of both group is assessed again and the before and after intervention results of intervention and control group are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091010076N6**
Registration date: **2016-08-13, 1395/05/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-13, 1395/05/23

Registrant information

Name
Maryam Saeedi
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 86 1417 3524
Email address
m.saeedi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Saveh medical sciences university

Expected recruitment start date

2015-06-20, 1394/03/30

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of progressive muscle relaxation on pruritus severity of hemodialysis patients

Public title

Effect of relaxation on pruritus

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: willing to participate in trial; hemodialysis history of 3 month; undergoing hemodialysis 3 times a week; history of pruritus for 2 week at least; having no dermal or non dermal disease producing pruritus(based on idea of physician); having

wholly awareness and ability of hearing for learning of relaxation method; having no physical disability or psychological disease such as severe stress and depression; not using anti pruritus drugs. Exclusion criteria: Not doing relaxation or don't complete the relaxation diary; use of anti pruritus drugs in research phase.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Saveh university of medical sciences

Street address
Saveh university of medical sciences, Taleghani St., Saveh

City
Saveh

Postal code

Approval date
2015-05-22, 1394/03/01

Ethics committee reference number
IRSAVEHUMS.REC1394.04

Health conditions studied

1

Description of health condition studied
End stage kidney disease

ICD-10 code
N18.5

ICD-10 code description
End stage kidney disease

Primary outcomes

1

Description
Pruritus

Timepoint
One month

Method of measurement
Pruritus scale and visual analogue scale for pruritus

Secondary outcomes

1

Description
Pruritus severity

Timepoint
One month

Method of measurement
Pruritus severity scale

Intervention groups

1

Description
Progressive muscle relaxation in intervention group for one month that was done daily by patient in 15 to 20 minutes.

Category
Behavior

2

Description
no intervention in control group

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hemodialysis center of Modares hospital of Saveh

Full name of responsible person
Maryam Saeedi

Street address

Modarres Hospital, Modarres Square, Saveh

City

Saveh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Saveh university of medical sciences

Full name of responsible person

Dr. Mahmood Karimi

Street address

Saveh university of medical sciences, Taleghani St., Saveh

City

Saveh

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, Saveh 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

Saveh university of medical sciences

Full name of responsible person

Maryam Saeedi

Position

MS/ Faculty member

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