

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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)

##### Phone

+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**

**Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*