

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The Effect of Effleurage massage With Sesame oil On Hemodialysis patient's Restless leg syndrome

#### Protocol summary

##### Summary

The aim of this study was to determine the effect of Effleurage massage with sesame oil on hemodialysis patient's restless leg syndrome. This study is a randomized clinical trial that was done on chronic renal failure patients undergoing hemodialysis that were referred to the Hemodialysis wards of Ziaei Hospital of Ardakan city and Imam Jafar Sadeq Hospital in Meybod city in 2016. The sampling method was convenience. 60 patients that had the inclusion criteria were chosen and then were randomly allocated to two groups consisting of 30 patients. The intervention group received leg and foot Effleurage massage with sesame oil for four weeks, twice a week, and each time for 10 minutes respectively. The Control group received usual care of hemodialysis patients. One week after the end of the study, the patients completed the study tools. The results were analyzed with the chi square and t test in SPSS version 19. Inclusion criteria: Chronic renal failure patients on Hemodialysis regularly for at least 6 months prior to Restless legs syndrome; Regularly scheduled dialysis at least twice a week; Ranging in age from 18 to 65 years; Hb higher than 10 mg per deciliter. Exclusion criteria: Uncooperative patient or died during the study; Allergy symptoms during the study; Injury or accident during study treatment; Start a new drug treatment intervention in the study by psychiatrists; Aggravate RLS symptoms and the lack of control; Addiction and substance abuse, lack of disease psychosis, dementia and mental retardation; Movement disorders in legs; There is an open wound below the knee to the foot.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016111030815N1**

Registration date: **2017-03-16, 1395/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-03-16, 1395/12/26

##### Registrant information

###### Name

Heydar Kalantari

###### Name of organization / entity

Shahid Sadoughi Yazd University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 32244658

###### Email address

kalantari@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Sadoughi University of Medical Sciences Yazd

##### Expected recruitment start date

2016-03-19, 1394/12/29

##### Expected recruitment end date

2016-12-19, 1395/09/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Effleurage massage With Sesame oil On Hemodialysis patient's Restless leg syndrome

##### Public title

The Effect of Massage with sesame oil on Hemodialysis

patient's leg pain

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria:Chronic renal failure patients On Hemodialysis regularly For at Least6 months prior to Restless legs syndrome:Regularly scheduled dialysis at least twice a week!Ranging in age from 18 to 65 years:Hb higher than 10 mg per deciliter Exclusion criteria:Uncooperative patient or died during the study:Allergy symptoms during the study:Injury or accident during study treatment:Start a new drug treatment intervention in the study by psychiatrists:Aggravate RLS symptoms and the lack of control:Addiction and substance abuse, lack of disease psychosis, dementia and mental retardation:Movement disorders in legs:There is an open wound below the knee to the foot.

## Age

From **77 years** old to **30 years** old

## Gender

Both

## Phase

N/A

## 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

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Sadoughi University of Medical Sciences Yazd

##### Street address

Yazd.Shahid Sadoughi University of Medical Sciences Yazd

##### City

ARDAKAN

##### Postal code

8944158318

#### Approval date

2016-02-19, 1394/11/30

#### Ethics committee reference number

IR.SSU.MEDICINE.REC.1394.469

## Health conditions studied

### 1

#### Description of health condition studied

Hemodialysis patient's

#### ICD-10 code

Z49

#### ICD-10 code description

Care involving dialysis

## Primary outcomes

### 1

#### Description

Restless leg syndrome

#### Timepoint

Baseline,First week,Second week,Third week,Forth week,One week after the end of the study

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Restless legs

#### Timepoint

Baseline,First week,Second week,Third week,Forth week,One week after the end of the study

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

This study is a randomized clinical trial that was done on chronic renal failure patients undergoing hemodialysis that were referred to the Hemodialysis wards of ziaei Hospital of ardakan city and emam jafar sadegh Hospital in meybod city. The sampling method was convenience.60 patients that had the inclusion criteria were chosen and then were randomly allocated to two groups consisting of 30 patients. The intervention group received leg and foot Effleurage massage with sesame oil for four weeks, twice a week, and each time for 10 minutes, one hour after the start of dialysis patients, at a rate of 30 to 60 cc respectively. One week after the end of the study, the patients completed the study tools. The results were analyzed with the , chi square and t test in SPSS version 19.

#### Category

Other

### 2

#### Description

The Control group received usual care of hemodialysis patients.

**Category**

Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Ardakan Ziaei hospital

**Full name of responsible person**

Mr.Dehstani

**Street address**

Ziaei Hospital Of Ardakan

**City**

Ardakan

2

**Recruitment center**

**Name of recruitment center**

Emam jafar sadegh Hospital Of Meybod

**Full name of responsible person**

kalantari

**Street address**

Emam jafar sadegh Hospital Of Meybod

**City**

Meybod

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences Yazd,  
Iran

**Full name of responsible person**

Dr.Ghasemi

**Street address**

International Campus Yazd,Iran

**City**

Ardakan

**Grant name**

0

**Grant code / Reference number**

0

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

Yes

**Title of funding source**

Shahid Sadoughi University of Medical Sciences Yazd,  
Iran

**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**

Shahid Sadoughi University of Medical Sciences Yazd,  
Iran

**Full name of responsible person**

kalantari Heydar

**Position**

Msc Student in Adult Critical Care Nursing

**Other areas of specialty/work**

**Street address**

Ziaei hospital of Ardakan

**City**

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8951869916

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**Fax**

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**Email**

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0

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences Yazd,  
Iran

**Full name of responsible person**

Phd,Vaezi Ali akbar

**Position**

Phd,Assistant Professor

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

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Shahid Sadoughi University of Medical Sciences Yazd,  
Iran

**Full name of responsible person**

Heydar Kalantari

**Position**

Msc Student in Adult Critical Care Nursing

**Other areas of specialty/work**

**Street address**

Ziaei hospital of Ardakan

**City**

Ardakan

**Postal code**

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**Fax**

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**Email**

Perances3499@yahoo.com

**Web page address**

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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*