

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### A comparison Study of the effect of massage therapy with and without Essential oils on uremic pruritus of hemodialysis women who referred to teaching hospitals in Urmia in 2019-20

#### Protocol summary

##### Study aim

Determination and comparison of the effect of massage with and without aromatic oils on uremic pruritus of women undergoing hemodialysis referred to Urmia educational-medical centers in 1389-99

##### Design

The present study is a clinical trial to evaluate pruritus in hemodialysis patients. In this Research among 100 hemodialysis female patients , 100 patients were selected by convenience sampling method and randomly assigned using web-based software Randomizer was divided into one control group and three intervention groups (lavender, violet and blank massage groups) (25 patients each). The subjects of this study are parallel and non-blinded groups.

##### Settings and conduct

The present study is a clinical trial to evaluate pruritus in hemodialysis patients. In this Research among 100 hemodialysis patients referred to Imam Khomeini and Taleghani educational centers of Urmia, 100 patients were selected by convenience sampling method and randomly assigned to a control group and three groups. Intervention (lavender, violet and blank massage groups) will be divided. The researcher will refer to the Urmia training centers by receiving a code of ethics and a formal letter from the university. The study and the method of the research work give them written informed consent to participate in the study Dead. The researcher will collect data in three stages.

##### Participants/Inclusion and exclusion criteria

1) At least 6 months of hemodialysis treatment 2) Willingness to participate in the study 3) No other skin problems 4) womans over 18 and under 85 years 1) Kidney transplant or no hemodialysis for any reason 2) pregnancy, lactation and diabetes 3) Use other pruritus control methods

##### Intervention groups

Group 1) Massage with lavender oil Group 2) Massage with violet oil Group 3) Massage without oil Group 4) Control group

##### Main outcome variables

Uremic pruritus

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191205045624N1**

Registration date: **2019-12-13, 1398/09/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-13, 1398/09/22**

Update count: **0**

##### Registration date

2019-12-13, 1398/09/22

##### Registrant information

##### Name

Zahra Heidarnia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3275 4916

##### Email address

zheidarnia62@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-22, 1398/09/01

##### Expected recruitment end date

2020-03-19, 1398/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparison Study of the effect of massage therapy with and without Essential oils on uremic pruritus of hemodialysis women who referred to teaching hospitals in Urmia in 2019-20

**Public title**

A comparison Study of the effect of massage therapy with and without Essential oils on uremic pruritus of hemodialysis women

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

1) Female gender (because she is a female researcher and personally massage the patients, she chooses only the female sample to observe her ethical and convenience in conducting the research) 2) At least 6 months of hemodialysis treatment 3) a history of at least two weeks uremic pruritus 4) No history of psychiatric treatment and mourning for the past 6 months 5) Willingness to participate in the study 6) No other skin problems 7) Lack of infectious diseases, AIDS and hepatitis 8) Failure to receive any treatment that disrupts mental ability, memory or thinking 9) Have dialysis sessions at least 3 times a week 10) Age over 18 and less than 85 years

**Exclusion criteria:**

1) Kidney transplant or no hemodialysis for any reason 2) pregnancy, lactation and diabetes 3) Use other pruritus control methods

**Age**

From **18 years** old to **85 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Based on the inclusion criteria, 100 patients were selected by convenience sampling method and randomly assigned using Randomizer web-based software that was able to generate random sequences by blocking method and assigned the samples to a control group (Group I). And will be divided into three intervention groups (groups II, III, IV) (25 patients each).

**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**

Urmia University of Medical Sciences

**Street address**

Urmia, Nazlo Campus, Urmia University of Medical Sciences, School of Nursing and Midwifery

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5756115111

**Approval date**

2019-09-04, 1398/06/13

**Ethics committee reference number**

IR.UMSU.REC.1398.212

**Health conditions studied****1****Description of health condition studied**

Uremic pruritus in hemodialysis women

**ICD-10 code**

N18.5

**ICD-10 code description**

Chronic kidney disease, stage 5

**Primary outcomes****1****Description**

Uremic pruritus

**Timepoint**

Before and after intervention

**Method of measurement**

Pruritus Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Massage the forearm and arm

without fistula with lavender oil in the amount of 3-5 cc of lavender oil for 20 minutes (forearm and arm each 10 minutes).

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: Massage the forearm and arm without fistula with violet oil in the amount of 3-5 cc of lavender oil for 20 minutes (forearm and arm each 10 minutes).

**Category**

Treatment - Drugs

**3**

**Description**

Intervention group: Fistula-free forearm and arm massage will be performed without using lavender and violet oil for 20 minutes (forearm and arm each 10 minutes).

**Category**

Treatment - Other

**4**

**Description**

Control group: In this group there are hemodialysis patients with no intervention. Patients in this group are only monitored.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Urmia Imam Khomeini and Taleghani Hospitals

**Full name of responsible person**

Zahra Heidarnia

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School of Nursing and Midwifery, Urmia University of Medical Sciences, Urmia, Iran

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Iraj Mohebbi, Deputy of Research and Technology of Urmia University of Medical Sciences

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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**

Oroumia 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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Zahra Heidarnia

**Position**

MSc Student of Critical Care Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

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science Committee, Associate Professor of Nursing Education  
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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

اطلاعات بیشتری وجود ندارد

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available