

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

Street address

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

City

Urmia

Province

West Azarbaijan

Postal code

5756115111

Phone

+98 44 3275 4916

Fax

+98 44 3275 4921

Email

zheidarnia62@gmail.com

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

Street address

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

City

Urmia

Province

West Azarbaijan

Postal code

5756115111

Phone

+98 44 3275 4916

Email

zheidarnia62@gmail.com

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

Street address

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

City

Urmia

Province

West Azarbaijan

Postal code
5756115111
Phone
+98 44 3275 4916
Email
zheidarnia62@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Hossein Habibzadeh
Position
science Committee, Associate Professor of Nursing Education
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Urmia University of Medical Sciences, Urmia, Iran
City
Urmia
Province
West Azarbaijan
Postal code
5756115111
Phone
+98 44 3275 4916
Email
Habibzadeh@yahoo.com

Person responsible for updating data

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
Street address
School of Nursing and Midwifery, Urmia University of Medical Sciences, Urmia, Iran
City
Urmia
Province
West Azarbaijan
Postal code
5756115111
Phone
+98 44 3275 4916
Email
zheidarnia62@gmail.com

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