

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of massage and topical rubbing of violet oil on inflammatory factors in hemodialysis patients

Protocol summary

Study aim

Comparison of inflammatory factors before and after intervention in massage group with or without violet oil

Design

In this randomized clinical trial, 44 hemodialysis patients will select and, after completing the full description of the study, they will receive written consent and were randomly divided into two groups by block method. In both groups, for the first two weeks, the severity of itching and the measurement of inflammatory factors, phosphorus and parathormone will complete as control stage for two weeks. Then, in group 1, massage, and in group 2, massages with violet oil in the other hand without fistula will prescribe and after the intervention, the severity of itching and the measurement of inflammatory factors, phosphorus and parathormone will repeat, and finally, the results in each group will compare with their control stage and also between the two groups.

Settings and conduct

In group 1, massage and in group 2, massages with violet oil - prepared on the basis of sweet almond oil - for 6 sessions (two weeks) in the other hand without fistula will prescribe

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age of 18 - 80 years History of hemodialysis over three months Lack of any skin problem causing itching Having itching within 2 weeks before starting the sampling Exclusion Criteria: The patient's kidney transplant during the study Sensitivity to used oil Fistula in the study Patient's personal decision to exit the plan Itching of the patient due to skin problem Peritoneal dialysis

Intervention groups

Massage with or without violet oil

Main outcome variables

Changes in serum inflammatory factors before & after intervention

General information

Reason for update

Acronym

UP , HD

IRCT registration information

IRCT registration number: **IRCT20170607034382N3**

Registration date: **2019-01-07, 1397/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-07, 1397/10/17**

Update count: **0**

Registration date

2019-01-07, 1397/10/17

Registrant information

Name

Seyed Majid Ghazanfari

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4423 1041

Email address

ghazanfarim941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of massage and topical rubbing of violet oil on inflammatory factors in hemodialysis patients

Public title

The effect of massage and violet oil on inflammatory factors in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

History of hemodialysis over three months
Lack of any skin problem causing itching within 2 weeks before starting the sampling
itching
Age of 80 - 18 years

Exclusion criteria:

The patient's kidney transplant during the study
Sensitivity to used oil
Fistula in the study
Patient's personal decision to exit the plan

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized using random numbers table

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**

Medical Ethics Committee of Mashhad University of Medical Sciences

Street address

Faculty of Iranian and complementary Medicine, Campus University, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-12-01, 1397/09/10

Ethics committee reference number

IR.MUMS.REC.1397.246

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

Pruritus

ICD-10 code

N17-N19

ICD-10 code description

End stage kidney disease: on dialysis

2**Description of health condition studied**

Pruritus in Hemodialysis Patients

ICD-10 code

N17-N19

ICD-10 code description

End stage kidney disease: on dialysis

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

Inflammatory factors

Timepoint

Before and after the study

Method of measurement

questionnaire

Secondary outcomes

empty

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

Intervention group: Massage without oil

Category

Treatment - Devices

2**Description**

Intervention group: Massage with oil

Category

Treatment - Devices

Recruitment centers**1****Recruitment center**

Name of recruitment center

Montasereyyeh Hospital
Full name of responsible person
Seyyed Majid Ghazanfari
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Imam Khomeini 25 - Imam Khomeini Street - Golestan
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Web page address
<http://tim.mums.ac.ir/index.php/2016-04-23-07-39-25>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyyed Majid Ghazanfari
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Faculty of Iranian and complementary Medicine,
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tim@mums.ac.ir
Web page address
<http://tim.mums.ac.ir/index.php/2016-04-23-07-39-25>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

50

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
Mashhad University of Medical Sciences
Full name of responsible person
Seyyed Majid Ghazanfari
Position
Persian Traditional Medicine Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Roshanak Salari
Position
Assistant Professor
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<https://fa.irct.ir/user/trial/26282/view>

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Seyyed Majid Ghazanfari

Position

Persian Traditional Medicine Student

Latest degree

Medical doctor

Other areas of specialty/work

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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

Because of ethical principles and assuring patients that their specifications are not disclosed

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Statistical results

When the data will become available and for how long

2019

To whom data/document is available

researchers

Under which criteria data/document could be used

Continue the research

From where data/document is obtainable

Mashhad University of Medical Sciences

What processes are involved for a request to access data/document

Written request . University agreement. Delivery of information

Comments