Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 andwere 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, phosphoro and parathormomean will complet 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 prescrib and after the intervention, the severity of itching and the measurement of inflammatory factors, phosphor 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 prescrib

Participants/Inclusion and exclusion criteria
inclusion Criteria: Age of 80 - 18 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)

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+98 51 4423 1041

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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 Having 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
Street address
Imam Khomeini 25 - Imam Khomeini Street - Golestan Street - Mashhad
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Sponsors / Funding sources

1

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Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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
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

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Person responsible for updating data

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Web page address
http://tim.mums.ac.ir/index.php/2016-04-23-07-39-25

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