Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

investigating the effect of effleurage massage and diluted vinegar solution on relieving pruritus among patients undergoing hemodialysis

Protocol summary

Study aim

Investigating the effect of effleurage massage and diluted vinegar solution on relieving the pruritus of hemodialysis patients in Bandar Abbas educational-treatment hospitals

Design

Each patient based on receiving a code from 0 to 60, is placed into one of groups (investigation or control) due to random number table

Settings and conduct

The study is a clinical trial and the samples were placed into two groups of intervention and control using a random number table and intervention group received the effleurage massage and diluted vinegar solution and control group received only routine care of the unit. The place of performing research was in Bandar_abbas educational-treatment hospitals . This study was two-sided and a valuator completed the questionnaires using the patient identification and statistical analyzer analyzed the data using the group number.

Participants/Inclusion and exclusion criteria

Include: All patients over the age of 18 who have been treated for hemodialysis for more than three months and complain of uremic urethra and dialysis three times a week and undergo hemodialysis every 3-5 hours.
Exclude: Having massage prohibition, sensitivity to vinegar solution, lack of satisfaction, another skin problem other than uremic pruritus

Intervention groups

Intervention group receives effleurage massage and diluted vinegar solution and control group only receives routine care of the unit.

Main outcome variables

The investigation of effleurage massage and diluted vinegar solution on uremic pruritus.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160209026483N2**
Registration date: **2018-04-22, 1397/02/02**
Registration timing: **retrospective**

Last update: **2018-04-22, 1397/02/02**
Update count: **0**

Registration date

2018-04-22, 1397/02/02

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3223 2142

Email address

h_khoshnou@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2017-07-15, 1396/04/24

Actual recruitment start date

2017-07-01, 1396/04/10

Actual recruitment end date

2017-07-15, 1396/04/24

Trial completion date

empty

Scientific title

investigating the effect of effleurage massage and diluted vinegar solution on relieving pruritus among patients undergoing hemodialysis

Public title
investigating the effect of effleurage massage and diluted vinegar solution on relieving pruritus among hemodialysis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Performing hemodialysis three times a week Age over 18 years History of hemodialysis more than three months Each hemodialysis session lasts for 3-5 hours
Exclusion criteria:
massage prohibition sensitivity to vinegar solution skin problem other than uremic pruritus lack of patient satisfaction
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
each patient entering the study received a code from 0 to 60, then the samples were divided into two groups of investigation and control using a random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
an evaluator who was not informed about which patient belongs to which group (intervention or control), completed the scales using the patient identification code. then the statistics analyzer analyzed the data using the group number(1,2).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences
Street address
South Resalat st
City
Bandar Abbas
Province
Hormozgan
Postal code
7916839319
Approval date
2017-06-12, 1396/03/22
Ethics committee reference number
hums.rec.1396.021

Health conditions studied

1

Description of health condition studied
itching in hemodialysis patients
ICD-10 code
z49
ICD-10 code description
Preparatory care for dialysis

Primary outcomes

1

Description
uremic pruritus
Timepoint
The evaluation of pruritus score in weeks 0,1,2,3,4 of study
Method of measurement
visual analog scale

Secondary outcomes

1

Description
scale of sleep disturbance
Timepoint
Before intervention and the first, second, third and fourth weeks of the intervention
Method of measurement
The questionnaire of sleep disturbance

Intervention groups

1

Description
Intervention group: Receiving effleurage massage and then diluted vinegar solution after each turn of performing hemodialysis
Category
Other

2

Description

Control group: Receiving standard care of the unit

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital and Children Hospital in Bandar Abbas

Full name of responsible person

Zeinab Rastgoo

Street address

South Resalat st.

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+98 76 3366 6368

Email

zrastgoo1362@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Doctor Teimoor Aghamolaei

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South Resalat st.

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Email

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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

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Zeinab Rastgoo

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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74851-33177

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

main outcome information

When the data will become available and for how long

starting the access period, six month after printing the results

To whom data/document is available

researchers working in academic and scientific institutes

Under which criteria data/document could be used

those with the same study and working in research institutes

From where data/document is obtainable

zrastgoo1362@gmail.com

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

with E-mail

Comments