Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of applying cold compress on the severity of uremic pruritus in hemodialysis patients: A clinical trial

Protocol summary

Study aim
Determining the effect of cold compress on the severity of uremic pruritus in hemodialysis patients
Design
clinical trial without control group and randomization
Settings and conduct
Participants complete the questionnaire before and four weeks after the intervention and score the severity of pruritus. A reminder table designed by the researcher is given to patients, including the number of itches per day and the usage of ice packs. Patients are asked to put jelly ice packs on itchy areas for 5-10 minutes between hemodialysis sessions whenever they experience pruritus. This study will be done in hemodialysis wards of Hashemi nezhad, Rasool Akram and Firoozgar Hospital
Participants/Inclusion and exclusion criteria
Inclusion criteria are No history of dermal and non-dermal itching diseases, No pregnancy and lactation, No hemodialysis due to acute renal failure, History of hemodialysis at least from 6 months ago, Suffering from pruritus at least for 2 weeks and exclusion criteria are Reluctance to continue participating in the study and Reluctance to use the cold compress
Intervention groups
Between their hemodialysis sessions, whenever itching occurs, put jelly ice packs which are provided for them first, in the freezer for 2 hours to freeze completely and then cover it with a layer of sterile gas which was also provided before, and then put it for five to ten minutes on the itchy areas
Main outcome variables
Number of the severity of uremic pruritus

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220506054751N1**
Registration date: **2022-05-23, 1401/03/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-23, 1401/03/02**
Update count: **0**
Registration date
2022-05-23, 1401/03/02

Registrant information
Name
Kimiya Babakhaniyan
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-23, 1401/03/02
Expected recruitment end date
2022-06-23, 1401/04/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of applying cold compress on the severity of uremic pruritus in hemodialysis patients: A clinical trial

Public title
Effect of cold compress on the severity of pruritus in hemodialysis patients

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
No history of dermal and non-dermal itching diseases like Atopic dermatitis and chronic liver disease No history of Allergy and chronic inflammation disorder No pregnancy and lactation No kidney transplantation No hemodialysis due to acute renal failure 18-60 years old patients Be able to read and write History of hemodialysis at least from 6 months ago Suffering from pruritus at least for 2 weeks Hemodialysis 3 times a week and each time for 4 hours Informed and conscious consent to participate in the study
Exclusion criteria:
Reluctance to continue participating in the study Reluctance to use the cold compress
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **55**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committees of Iran University of Medical Sciences
Street address
Hemmat hwy, next to Milad tower
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2022-04-08, 1401/01/19
Ethics committee reference number
IR.IUMS.REC.1401.011

Health conditions studied

1

Description of health condition studied
Uremic pruritus
ICD-10 code
L29
ICD-10 code description
Pruritus

Primary outcomes

1

Description
Number of the severity of pruritus based on Visual Analogue Scale
Timepoint
Rating the severity of pruritus will be done in the start of intervention and 4 weeks later
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Between their hemodialysis sessions, whenever itching occurs, put jelly ice packs which are provided for them first (placed in a sealed plastic bag, weighing 300 g and measuring 2 x 17 x 25 cm), in the freezer for 2 hours to freeze completely and then cover it with a layer of sterile gas which was also provided before, and then put it for five to ten minutes on the itchy areas
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Hashemi Nezhad hospital
Full name of responsible person
Kimiya Babakhaniyan
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2

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
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3

Recruitment center
Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Hossein Keivani
Street address
Iran University of Medical Sciences, next to Milad Tower, Hemmat Hwy
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Kimiya Babakhaniyan
Position
MSN student
Latest degree
Bachelor
Other areas of specialty/work
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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

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