

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8836 6311

###### Email address

babakhaniyan.ki@iums.ac.ir

##### 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****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

**Street address**

Valinejad St, Valiasr Ave

**City**

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**Province**

Tehran

**Postal code**  
1969714713  
**Phone**  
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support@hkc.ir

## 2

### Recruitment center

**Name of recruitment center**  
Firoozgar hospital  
**Full name of responsible person**  
Kimiya Babakhaniyan  
**Street address**  
Behafarin St, Karimkhan St, Valiasr sq  
**City**  
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**Province**  
Tehran  
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1593748711  
**Phone**  
+98 21 8214 1600  
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h\_firoozgar@yahoo.com

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### Recruitment center

**Name of recruitment center**  
Rasoul Akram hospital  
**Full name of responsible person**  
Kimiya Babakhaniyan  
**Street address**  
Niyayesh St, Sattarkhan St  
**City**  
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**Postal code**  
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**Email**  
rasoolhospital@tums.ac.ir

## 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  
**City**  
Tehran  
**Province**

Tehran  
**Postal code**  
1449614535  
**Phone**  
+98 21 8670 2503  
**Email**  
research\_m@iums.ac.ir

### 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

Nursery

#### Street address

Nursing school of Iran University of Medical Sciences,  
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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

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#### Position

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Kimiya Babakhniyan

**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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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