

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of cool dialysate on sexual dysfunction in hemodialysis patients in mashhad hemodialysis centers

#### Protocol summary

##### Study aim

The effects of cool dialysate on sexual disorders in hemodialysis patients

##### Design

60 Patients with sexual disorders are randomly divided into two groups: cool dialysate and standard dialysate. The study is a three-blind clinical trial with parallel groups.

##### Settings and conduct

This study will be performed on 30 patients in the experimental group and 30 patients in the control group in Nikan Farda and Tabarsi shomali 17 Mashhad dialysis centers who met the inclusion criteria and were randomly divided. Patients in both the study group, statistical analyzer and the researcher will be blinded to this study. Using International Erectile Function Index (IIEF) and Female Sexual Function Index (FSFI), patients' sexual performance will be assessed in both groups before and one month after intervention in both groups. The two groups data will be analyzed using statistical tests.

##### Participants/Inclusion and exclusion criteria

Being Married, having partner, performing hemodialysis twice or more a week. exclusion criteria: Sexual drug usage, surgery on genital area due to sexual disorders, hyperparathyroidism, bisexuality, hemoglobin under 9 mg/dl, having major depression

##### Intervention groups

In the intervention group hemodialysis will be done using dialysis solution with a temperature of 35.5 ° C. In control group hemodialysis will be done with standard solution temperature of 37 ° C and will be assessed its effect on sexual disorders.

##### Main outcome variables

Sexual function score of male and female patients

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200124046235N1**  
Registration date: **2020-04-01, 1399/01/13**  
Registration timing: **retrospective**

Last update: **2020-04-01, 1399/01/13**

Update count: **0**

##### Registration date

2020-04-01, 1399/01/13

##### Registrant information

###### Name

Rahele Hasanpour Moghadam

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3711 2578

###### Email address

hasanpourmr2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-09, 1398/11/20

##### Expected recruitment end date

2020-03-10, 1398/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of cool dialysate on sexual dysfunction in hemodialysis patients in mashhad hemodialysis centers

## Public title

The effects of cool dialysate on sexual dysfunction in hemodialysis patients

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Being married Having a sexual partner performing hemodialysis twice and more a week

### Exclusion criteria:

taking sex drugs Surgery on the genital area due to sexual disorders Hyperparathyroidism Bisexuality Hemoglobin below 9 mg/dl major depression

## Age

From **20 years** old to **75 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

First samples will be selected by convenience method according to inclusion and exclusion criteria. Then random assignment will be used with permuted blocking. R Software will be used to get the blocks. The blocks are made up of 4 English letters (A,B,C,D). A ,B will be considered for the intervention group, and other three letters (C, D) will be considered for the control group. The blocks will be randomly selected in blindfolded manner. Each block will determine the order of entry in the intervention and control groups. Assuming choosing the DACB block means from left hand, first and third, respectively, will be located in the control group, and the second and fourth of participants will be located in the intervention group, respectively.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

In this study, patients in both intervention and control groups will be blinded using a paper cover made by the researcher assistance with the specified dimensions and placed on the dialysis machine's temperature monitor, The researcher will be blinded by the researcher assistance by handing out the questionnaires and the data analyzer will be blinded by the coding of the patients.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

National Committee for Ethics in Biomedical Research

##### Street address

Pardis of University of Medical Sciences, Nuclear Martyrs Boulevard, Sabzevar

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9613873136

#### Approval date

2020-01-14, 1398/10/24

#### Ethics committee reference number

IR.MEDSAB.REC.1398.086

## Health conditions studied

### 1

#### Description of health condition studied

Sexual disorders

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

sexual function score of female patients <sup>s</sup>

#### Timepoint

Before intervention and one month after the intervention

#### Method of measurement

Female Sexual Function Index

### 2

#### Description

sexual function score of male patients

#### Timepoint

Before intervention and one month after the intervention

#### Method of measurement

International Index of Erectile Function

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: The temperature of hemodialysis fluid (dialysate) is set at 35.5 ° C while the type of filter, filter ultrafiltration coefficient, and blood flow rate will not change. All patients will undergo hemodialysis with Fresenius B-4008. The filters used for hemodialysis during the study will be fixed for each patient. The hemodialysis flow rate solution in all patients will be 500 ml / min. The temperature of the hemodialysis unit will be maintained at 22 ° C throughout the study. The vital signs of the patients, especially the body temperature, will be monitored every hour. Patients in the intervention group will undergo dialysis with cold solution of 35.5 ° C for 3 times each week for 4 hours each time.

### Category

Rehabilitation

## 2

### Description

Control group: The temperature of hemodialysis fluid (dialysate) is set at 37 ° C while the type of filter, filter ultrafiltration coefficient, and blood flow rate will not change. All patients will undergo hemodialysis with Fresenius B-4008. The filters used for hemodialysis during the study will be fixed for each patient. The hemodialysis flow rate solution in all patients will be 500 ml / min. The temperature of the hemodialysis unit will be maintained at 22 ° C throughout the study. The vital signs of the patients, especially the body temperature, will be monitored every hour. Patients in the control group will undergo dialysis with cold solution of 37 ° C for 3 times each week for 4 hours each time.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Nikan Fada Hemodialysis Center

##### Full name of responsible person

Fateme Nazemian

##### Street address

Nikan Farda dialysis center, Shahid Fakouri 34, Shahid Fakouri St.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9178143655

##### Phone

+98 51 3711 2578

##### Email

Nazemianf@mums.ac.ir

## 2

#### Recruitment center

##### Name of recruitment center

Tabarsi Shomali17

##### Full name of responsible person

Fateme Nazemian

##### Street address

Tabarsi Shomali17 Dialysis Center, Tabarsi Shomali17, Tabarsi Shomali street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9156779348

##### Phone

+98 51 3212 0005

##### Email

nazaria2@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Ferashte Gharat

##### Street address

Vice-Chancellor for Research and Technology, Pardis of University of Medical Sciences, Shohadaie hastee Boulevard, Sabzevar

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617913112

##### Phone

+98 51 3401 8484

##### Email

vc.Research@medsab.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sabzevar University of Medical Sciences

#### Proportion provided by this source

1

#### 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

Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Rahele Hasanpour Moghaddam

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No61, Moasavi Gochni17, Mosavi Ghochani street

**City**

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**Postal code**

9188655715

**Phone**

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**Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Position**

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## Person responsible for updating data

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is 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**

No - There is not a plan to make this available

**Title and more details about the data/document**

Participants' personal data will not be shared.

**When the data will become available and for how long**

Participants' personal data will not be shared.

**To whom data/document is available**

if the data is required it will be made available to scientific and academic institutions , with due regard for the confidentiality of information.

**Under which criteria data/document could be used**

The results of the study will be communicated to the patients themselves.

**From where data/document is obtainable**

if necessary, corresponding author of the manuscript will provide the data to scientific institutions

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

Editor of the journal can be applied the data and corresponding author should delivered data to them via email within a month

**Comments**