

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 *

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

Sbzevar

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

Mashhad

Province

Razavi Khorasan

Postal code

9188655715

Phone

+98 51 3711 2578

Email

hasanpourmr2@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Rahele Hasanpour Moghaddam

Position

Nurse

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Other areas of specialty/work

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Phone

+98 51 3711 2578

Email

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Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Rahele Hasanpour Moghaddam

Position

nurse

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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