Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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)

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+98 51 3711 2578

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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 ʼ
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
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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
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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

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Person responsible for scientific inquiries

Contact

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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

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Position
nurse

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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