Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Cool Dialysate on Depression in Hemodialysis Patients

Protocol summary

Study aim
Determine the effect of cool dialysate on depression in patients with chronic renal failure undergoing hemodialysis

Design
66 Patients with depression are simple 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 33 patients in the experimental group and 33 patients in the control group in Sabzevar dialysis centers who met the inclusion criteria and were randomly divided. Patients in both the study group and the researcher will be blinded to this study. Depression during hemodialysis will be assessed by Beck Depression Inventory 2 before and after the intervention and two weeks after the intervention in both groups.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Having informed consent to participate in the study, Ages over 18 years of any gender, Have complete alertness and acceptable verbal and hearing ability to answer questions؛ Exclusion Criteria: Treated with antidepressant, Known hypothyroidism, Hemoglobin Less than 8 mg/dL.

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 depression.

Main outcome variables
Depression score on Beck Questionnaire 2

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200215046495N1**
Registration date: **2020-03-02, 1398/12/12**
Registration timing: **prospective**

Last update: **2020-03-02, 1398/12/12**
Update count: **0**

Registration date
2020-03-02, 1398/12/12

Registrant information
Name
Maryam Farhadi
Name of organization / entity
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Iran (Islamic Republic of)
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farhadim97@medsab.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-04-20, 1399/02/01
Expected recruitment end date
2020-07-21, 1399/04/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Cool Dialysate on Depression in Hemodialysis Patients

Public title
The Effect of Cool Dialysate on Depression
Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent to participate in the study Ages over 18 years of any gender Patient with a diagnosis of chronic renal failure (patients who have been hemodialysis for 6 months) Under hemodialysis 3 times a week and each session 4 hours Have complete alertness and acceptable verbal and hearing ability to answer questions Patients with KT/V greater than or equal to 1

Exclusion criteria:

Treated with antidepressants Malignancy Known hypothyroidism Patients with hemoglobin less than 8 mg/dL Patients whose access to the vessels is through a temporary catheter or Shaldon

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected by available sampling and will be randomly assigned to intervention and control groups using random allocation blocks.R Software will be used to get the blocks. The blocks are made up of 6 English letters (A,B,C,D,E,F). A ,B,C will be considered for the intervention group, and other three letters (D,E,F) 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 DCAFBE block means from left hand, first, fourth and sixth, respectively, will be located in the control group, and the second, third, and fifth of participants will be located in the intervention group, respectively. Thus, eleven blocks will be selected to complete the sampling.

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

Ethics committee of Sabzevar University of Medical Sciences

Street address

Block B, University of Medical Sciences Pardis, Above Unknown Martyrs, Nuclear Martyrs Boulevard

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.MEDSAB.REC.1398.116

Health conditions studied

1

Description of health condition studied

Chronic kidney disease, Under Hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Depression score on Beck Questionnaire 2

Timepoint

Measurement of depression score before and after the last intervention session (end of the 12th hemodialysis session) and two weeks after the intervention

Method of measurement

Beck Depression Inventory II (BDI-II)

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

Treatment - Other

2

Description

Control group: The temperature of the hemodialysis fluid is set at 37 ° C. While the type of filter, filter ultrafiltration, blood flow rate, and device type will be constant throughout the study. All conditions in the intervention group will be adjusted for the control group except dialysis temperature which will be set at 37° C.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasai Hospital

Full name of responsible person

Dr. Rad Mustafa

Street address

Vasei Hospital, Nuclear Martyrs Boulevard

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9617747431

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2

Recruitment center

Name of recruitment center

Kashif Dialysis Center

Full name of responsible person

Dr. Rad Mustafa

Street address

First Floor, Nikan Doctors Building, 13 Kashi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Ghorat Fereshteh

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Farhadim356@gmail.com

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

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

Sabzevar University of Medical Sciences

Full name of responsible person

Farhadi Maryam

Position

Nursing Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
Information on the main outcome (severity of depression) will be shared.
When the data will become available and for how long
Nine months after the results were published
To whom data/document is available
Data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Don't use submitted data to print articles.
From where data/document is obtainable
Dr. Rad Mostafa , Email: mostafarad633@yahoo.com Phone No: 0098 51 44018300
What processes are involved for a request to access data/document
Upon request by the supervisor, Dr. Rad Mostafa will be provided with documentation and files at the Secretariat.
Comments