Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation the effectiveness of comprehensive nursing care on uremic pruritus, sleep quality and dialysis adequacy in patients undergoing hemodialysis treatment

Protocol summary

Study aim
Determining the effect of comprehensive nursing care on uremic rash, sleep quality and dialysis adequacy in hemodialysis patients

Design
This study is a controlled clinical trial (single-blind) with a control group, with parallel groups, one blind, randomized on 70 patients in hemodialysis patients undergoing treatment in the hemodialysis department of Ali Ibn Abitaleb Hospital (A.S.). They are Zahedan, who have consented to participate in this research and meet the criteria for entering this study.

Settings and conduct
The research sample includes all hemodialysis patients undergoing treatment in the hemodialysis department of Ali Ibn Abi Talib (AS) Zahedan Hospital.Before the intervention, the demographic characteristics form, the degree of itching by completing the 5-dimensional scale of itching and their sleep quality through the Pittsburgh sleep index standard questionnaire, as well as the adequacy of dialysis is measured based on the formula. The control group will receive routine nursing and the intervention group will receive comprehensive nursing and after 3 months againare re-examined

Participants/Inclusion and exclusion criteria
Inclusion :Having a history of hemodialysis for at least three months before Having arteriovenous fistula... Exclusion:refusal to participation in the research death, travel

Intervention groups
The intervention group will receive comprehensive nursing, necessary training for the intervention group in five sessions, which include: health education, nutritional guidance, dialysis care (before, during and after dialysis), psychological interventions and daily care, which lasts 3 months will be done and the control group will receive routine nursing care.

Main outcome variables
uremic rash, sleep quality, dialysis adequacy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231021059797N1**
Registration date: **2023-11-13, 1402/08/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-13, 1402/08/22**
Update count: **0**

Registration date
2023-11-13, 1402/08/22

Registrant information
Name
atefeh fahraji
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 54 3326 0926
Email address
atefeh.fahrajii@zbum.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-06, 1402/08/15
Expected recruitment end date
2024-02-04, 1402/11/15
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effectiveness of comprehensive nursing care on uremic pruritus, sleep quality and dialysis adequacy in patients undergoing hemodialysis treatment

Public title

Investigation the effectiveness of comprehensive nursing care on uremic pruritus, sleep quality and dialysis adequacy in patients undergoing hemodialysis treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the research over 18 years of age Having a history of hemodialysis for at least three months before Having arteriovenous fistula Not suffering from heart diseases, infectious diseases, diseases related to other serious disorders at least one month before the study Performing hemodialysis three times a week for four hours each time The same type of ultrafiltration of filter and round device during the study for each patient Absence of liver problems No drug addiction

Exclusion criteria:

Withdrawal from participation in the pageant death, travel Getting other diseases (infectious, cardiac, etc.) while doing research The need to use drugs that affect uremic itching and their sleep quality while conducting research. Having skin diseases or sleep disorders while doing research Change in the dialysis pattern (number of sessions, dialysis hours, filter type, dialysis machine cycle, etc.) for any reason Being in the link list Drug use during the research period

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, first, a list of patients who meet the research inclusion criteria will be prepared, and then by random allocation, the first person selected will be in the intervention group and the second person will be in the control group. It will be continued that all research samples are in one of two intervention or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be conducted as a controlled clinical trial (single-blind, meaning that the subjects do not know which of the groups they are in).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zabul University of Medical Sciences

Street address

Sistan and Baluchistan province, Zabul city, 11 Ferdowsi St., next to the registry office

City

zabol

Province

Sistan-va-Balouchestan

Postal code

9861734184

Approval date

2023-10-18, 1402/07/26

Ethics committee reference number

IR.ZBMU.REC.1402.081

Health conditions studied

1

Description of health condition studied

Patients treated with hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Comprehensive nursing care

Timepoint

for 3 months

Method of measurement

through the researcher

Secondary outcomes

1

Description

uremic pruritus

Timepoint

for 3 months

Method of measurement

Itching 5-dimensional scale questionnaire

2

Description

sleep quality

Timepoint

for 3 months

Method of measurement

Pittsburgh Sleep Index Standard Questionnaire

3

Description

Adequacy of dialysis

Timepoint

for 3 months

Method of measurement

Calculate the amount KT/V

Intervention groups

1

Description

Intervention group:

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Taleb (AS) Zahedan Hospital

Full name of responsible person

Dr.Kave Orei Yazdani

Street address

Persian gulf boulevard, Zahedan, Sistan and Baluchestan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Zabul University of Medical Sciences

Street address

Headquarters of Zabul University of Medical Sciences, Shahid Bagheri St, Jahad square, Zabol

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Web page address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zabol University of Medical Sciences

Proportion provided by this source

20

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

Zabol University of Medical Sciences

Full name of responsible person

Atefeh fahraji

Position

Master's student in internal surgical nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Milan7, Saadi66,Saadi street, Zahedan

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Dr. Hossein Shahdadi

Position
Member of the academic staff of the university

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Position
Master's student in internal surgical nursing

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There are no plans to publish

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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