Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of High flux with increasing blood flow rate on hemodialysis sleep quality in Shahid Rahnemoon Hospital of Yazd

Protocol summary

Study aim
The effect of High flux with increasing blood flow rate on hemodialysis sleep quality
Design
Using a random allocation software, 50 eligible patients were divided into two groups of test and control groups, for the test group, flux filter and the rounds of the pump of 350-250 ml / min were used. The control group will undergo routine dialysis. The Pittsburgh questionnaire will be completed by interview method at the beginning and after the study.
Settings and conduct
Hemodialysis department of Shahid Ranmon Hospital
Participants/Inclusion and exclusion criteria
The desire to participate in the study Having a history of hemodialysis for at least six months Perform hemodialysis 3 times per week for 4 hours Having no heart disease Age range 25-70years Exclusion criteria: Transfer to another health center Blood pressure less than 60/100 Patients with a history of sleep disorders of more than 7 according to the Pittsburgh Sleep Inventory Moderate and severe pain (score greater than 3 based on the numerical value of pain).
Intervention groups
50 dialysis patients with sleep disorders eligible who were randomly allocated into two groups of test and control, were control group with routine method and test groups by increasing the speed of the pump and the flux filters dialysed
Main outcome variables
sleep quality

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180703040322N1**
Registration date: **2019-01-09, 1397/10/19**
Registration timing: **retrospective**

Last update: **2019-01-09, 1397/10/19**
Update count: **0**
Registration date
2019-01-09, 1397/10/19

Registrant information
Name
Shahrbanoo Ghasemian
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-03-06, 1396/12/15
Expected recruitment end date
2018-04-20, 1397/01/31
Actual recruitment start date
2018-03-06, 1396/12/15
Actual recruitment end date
2018-04-20, 1397/01/31
Trial completion date
2018-04-20, 1397/01/31

Scientific title
The effect of High flux with increasing blood flow rate on hemodialysis sleep quality in Shahid Rahnemoon Hospital of Yazd

Public title
The effect of High flux with increasing blood flow rate on hemodialysis sleep quality in Shahid Rahnemoon

Hospital of Yazd

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The desire to participate in the study Having a history of hemodialysis for at least six months Perform dialysis Perform hemodialysis 3 times per week for 4 hours, Having no heart disease Age range 25-70 years

Exclusion criteria:

Transfer to another health center Blood pressure less than 60/100 Patients with a history of sleep disorders of more than 7 according to the Pittsburgh Sleep Inventory Moderate and severe pain (score greater than 3 based on the numerical value of pain).

Age

From **25 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Actual sample size reached: **50**

More than 1 sample in each individual

Actual sample size in each individual: **25**

26 people in each group

Randomization (investigator's opinion)

Randomized

Randomization description

52 samples were selected according to inclusion and exclusion criteria. After obtaining informed consent from patients to participate in the research using code 01 to code 052 instead of the name of each patient used. Then, with random allocation software, randomly assigned to two groups of intervention and control divided.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants were unaware of the allocation of study groups

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Department of Nursing, Nursing- Midwifery School, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

916877443

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

ir.ssu.rec.1396.196

Health conditions studied

1

Description of health condition studied

hemodyalis patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep quality is between 0 and 21, which means that the higher the score is, the lower the sleep quality.

Timepoint

0 and after 45 day

Method of measurement

Pittsburgh Questionnaire

Secondary outcomes

1

Description

hemodialysis quality

Timepoint

0 and after 45 days

Method of measurement

Laboratory indicators

Intervention groups

1

Description

Intervention group: "Intervention group:" 25 hemodialysis patients who were randomly assigned to the intervention group were hemodialized under dialysis with high flux and increses blood flow for 45 days.

Category

Treatment - Devices

2

Description
"control group": 25 hemodialysis patients was dialysed routinely for 45 days.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rahnemoon Hospital of Yazd
Full name of responsible person
shahrbanoo ghasemian
Street address
Department of Nursing, Nursing- Midwifery School, Shahid Sadoughi University of Medical Sciences, Yazd, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
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دکتر مسعود میرزایی
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Department of Nursing, Nursing- Midwifery School, Shahid Sadoughi University of Medical Sciences, Yazd, Iran
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Email
far.farnia@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Dr.Farahnaz Farnia
Position
Assistant professor
Latest degree
Ph.D.
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Nursery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Only the original outcome data will be available
When the data will become available and for how long
unknown
To whom data/document is available
Researchers at university centers
Under which criteria data/document could be used
Any analysis on the delivered data is allowed. Agreed with the researcher by email for other matters.
From where data/document is obtainable
Yazd University of Medical Sciences
What processes are involved for a request to access data/document
Applying from the university research vice president
Comments