

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Shahrbano Ghasemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4427 1241

Email address

sh.ghasemian@ssu.ac.ir

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

hemodialysis 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 hemodialyzed under dialysis with high flux and increases 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

City

yazd

Province

Yazd

Postal code

916877443:کد پستی

Phone

+98 35 3824 1754

Email

ghasemian2040@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

دکتر مسعود میرزایی

Street address

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

City

yazd

Province

Yazd

Postal code

916877443

Phone

+98 35 3824 1754

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.

Other areas of specialty/work

Nursery

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Shahid Sadoughi University of Medical Sciences, Yazd,
Iran

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Province

Yazd

Postal code

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Phone

+98 35 3824 1754

Email

far.farnia@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

shahrbanoo ghasemian

Position

nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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

City

yazd

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Yazd

Postal code

کد پستی: 916877443

Phone

+98 35 3824 1754

Email

ghasemian2040@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

shahrbano0 ghsemian

Position

nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Shahid Sadoughi University of Medical Sciences, Yazd,
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yazd

Province

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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

Yes - There is a plan to make this available

Statistical Analysis PlanUndecided - 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 usedAny 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