Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating The Effect of Inspiratory Muscle Training during Hemodialysis On Pulmonary Function, Sleep Quality And Quality of Life In End Stage Renal Disease Patients With Overload: A Randomized Clinical Trial

Protocol summary

Study aim
Determine The Effect of Inspiratory Muscle Training during Hemodialysis On Pulmonary Function, Sleep Quality And Quality of Life In End Stage Renal Disease Patients With Overload

Design
A controlled, parallel-group, single-blind, randomized trial, phase 2 clinical trial on 60 patients. The website https://www.sealedenvelope.com will be used for randomization.

Settings and conduct
The study will be conducted at Shahid Jalil Hospital, Yasuj. The intervention will be performed for 2 weeks using the SpiroXpert, a proprietary, pitot tube designed by SpiroXpert, proprietary designed pitot tube, floXpert, Iran . The study is single-blind. Due to the nature of the intervention (tail muscle exercises during hemodialysis), patients are aware of the intervention and there is no possibility of blinding them. However, in order to reduce bias in the evaluation of the results, the assessor responsible for measuring the outcome variables will be unaware of the allocation of patients to the intervention or control group.

Participants/Inclusion and exclusion criteria
Inclusion: The patient must have a history of dialysis for at least three months. The patient must have fluid overload. No cancer. Exclusion: Pregnancy and acute lung infection

Intervention groups
After Random Assignment To Two Intervention And Control Groups, The Intervention Group Will Undergo Intervention Using A Tailbone Strengthening Device Twice A Week For 6 Weeks. The Control Group Will Receive Standard Treatment.

Main outcome variables
Pulmonary Function; Quality of Life; Sleep Quality

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250708066408N1**
Registration date: **2025-07-26, 1404/05/04**
Registration timing: **prospective**

Last update: **2025-07-26, 1404/05/04**
Update count: **0**

Registration date
2025-07-26, 1404/05/04

Registrant information
Name
Fateme Golabi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 74 3232 5520
Email address
fatimagolabi89@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-08-06, 1404/05/15
Expected recruitment end date
2025-09-06, 1404/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Investigating The Effect of Inspiratory Muscle Training during Hemodialysis On Pulmonary Function, Sleep Quality And Quality of Life In End Stage Renal Disease Patients With Overload: A Randomized Clinical Trial

Public title
The Effect of Inspiratory Muscle Training on Breathing In Dialysis Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Has A History Of At Least 3 Months Of Dialysis No Lung Cancer Or Other Terminal Tumors

Exclusion criteria:
Long-Term Use Of Continuous Positive Pressure Breathing Apparatus

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The blocking method will be used to allocate individuals to the study groups. The advantages of blocked randomization are that the balance of the number of patients in each group is guaranteed. The groups are defined as codes A and B. Group A will be considered the intervention and group B the control. Before assigning individuals to one of the groups, a list of letters (A, B) in the form of blocks will be formed. This random assignment list will be formed by the reputable website https://www.sealedenvelope.com. Each of the referring and eligible individuals will be assigned to one of the groups according to the created list. To prevent the predictable risk of assigning individuals to different groups, blocks of different sizes (2; 4; 6 and 8) will be created. Blocks of two such as AB - blocks of four such as ABAB - blocks of six such as AABABB - blocks of eight such as ABBABABA.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study is single-blind. Due to the nature of the intervention (tail muscle exercises during hemodialysis), patients are aware of the intervention and there is no possibility of blinding them. However, in order to reduce bias in the assessment of the results, the assessor responsible for measuring the outcome variables will be unaware of the allocation of patients to the intervention or control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences

Street address
Shahid Motahari

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417

Approval date
2025-06-18, 1404/03/28

Ethics committee reference number
IR.YUMS.REC.1404.064

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease Patients

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Pulmonary Function

Timepoint
Before and Immediately After The Intervention

Method of measurement
Spirometry

2

Description
Quality of Life

Timepoint
Before and Immediately After The Intervention

Method of measurement
Kidney disease quality of life; KDQOL-SFTM 1.3

3

Description
Sleep Quality
Timepoint
Before and Immediately After The Intervention
Method of measurement
Petersburg Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 6 weeks of intervention using SpiroXpert, proprietary designed pitot tube, floXpert, Iran twice a week during dialysis
Category
Treatment - Devices

2

Description
Control group: Standard Treatment Based on Existing Guidelines
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Jalil Hospital
Full name of responsible person
Masoumeh Alizadeh
Street address
Gharani Blvd
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
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Phone
+98 74 3333 7001
Email
shahidjalil@yums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Sirous Salehnasab
Street address
Shahid Motahari
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Phone
+98 74 3334 6078
Email
research@yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj University of Medical Sciences
Proportion provided by this source
50
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
Yasouj University of Medical Sciences
Full name of responsible person
Sajad Hasanzadeh
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Shahid Zarei Educational Campus, Beach Park Towards Imam Sajjad (AS) Hospital, Yasuj
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Person responsible for scientific

inquiries

Contact

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Full name of responsible person
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Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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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 Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
One Month After The Completion Of The Intervention, The Data Of The Main Variables Of The Study Will Be Shared

When the data will become available and for how long
The Commencement Of The Access Period Is 3 Months After The Publication Of The Results.

To whom data/document is available
After The Publication Of The Article, All Individuals Will Have Access To Its Content.

Under which criteria data/document could be used
Individuals Associated With The Medical And Therapeutic Field May Utilize The Data From This Study To Conduct New Research

From where data/document is obtainable
By Official Email To The Corresponding Author

What processes are involved for a request to access data/document
The Applicant Must Submit Their Formal Request Via The Organization's Email To The Email Of The Responsible Author. The Responsible Author Will Provide The Information To The Applicant Within A Maximum Of Two Weeks Upon Confirmation Of The Information

Comments