

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the Effectiveness of Physical Activity During Dialysis on the Dialysis Adequacy, Hemodynamic Indices and Fatigue in Hemodialysis Patients

Protocol summary

Study aim

Evaluation of the effectiveness of physical activity during dialysis on dialysis adequacy, hemodynamic parameters and fatigue in hemodialysis patients

Design

A randomized, controlled, single blind, with parallel groups clinical trial

Settings and conduct

The place of study: Bushehr hospitals. This is a single blind study in which performers of paraclinical tests, the person who enters data into software, and the person who analyzes data will be kept unaware of the intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years old; History of dialysis more than 3 months; Ability to perform walking independently (at least 2 minutes); 4-hour dialysis tolerance in past sessions
Non inclusion criteria: The history of unstable angina and heart attack in the past month; History of congestive heart failure; Treatment with psychiatric drugs; History of hypokalemia ($K < 3.5 \text{ Meq/L}$)

Intervention groups

Intervention group: Patients undergoing hemodialysis treatment who do physical activity for half an hour during dialysis and in the first two hours of dialysis using a pedal that is installed at the bottom of the bed. Control group: Patients undergoing hemodialysis treatment who received routine four-hour hemodialysis.

Main outcome variables

Dialysis adequacy, fatigue, blood pressure, pulse, respiration, temperature and O₂ saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150529022466N15**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **retrospective**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

Shahnaz Pouladi

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effectiveness of Physical Activity During

Dialysis on the Dialysis Adequacy, Hemodynamic Indices and Fatigue in Hemodialysis Patients

Public title

The effect of physical activity during dialysis on dialysis adequacy, hemodynamic indicators and fatigue in patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years old
History of hemodialysis more than 3 months
Ability to perform walking independently (at least 2 minutes)
4-hour dialysis tolerance in past sessions
No history of hypokalemia ($K < 3.5$ Meq/L)

Exclusion criteria:

Having problems with the musculoskeletal system
Systolic blood pressure greater than or equal to 160 mmHg or diastolic blood pressure greater than or equal to 120 mmHg
Having vascular access in the lower extremities
History of unstable angina and heart attack in 1 last month
History of congestive heart failure
Treatment with psychotropic drugs

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting all available participants based on inclusion criteria, randomization will be done using simple randomization method and statistical software.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the study, each participant will have a code that only the researcher will have access to, and the participant's name will not be specified for the outcomes evaluator and data analyzer. Paraclinical tests performance, record data and enter data into the software for analysis using code and without revealing the study group and name.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Bushehr University of Medical Sciences

Street address

Sabzabad Ave.

City

Bushehr

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Boushehr

Postal code

7518759577

Approval date

2019-12-22, 1398/10/01

Ethics committee reference number

IR.BPUMS.REC.1398.130

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease (ESRD), Hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Dialysis adequacy which is assessed by measuring the blood urea nitrogen levels before and after dialysis, the amount of fluid excreted from the patient and the weight after dialysis.

Timepoint

It is measured before the start of the study and after each dialysis session. Then the average is estimated at the end of the one month study period.

Method of measurement

Dialysis adequacy calculation software and Kt / V

2

Description

Fatigue

Timepoint

Before and after the one month study period

Method of measurement

FSS questionnaire

3

Description

blood pressure

Timepoint

Before and after dialysis and at each dialysis session until the end of the study period

Method of measurement

Using a digital device

4

Description

pulse

Timepoint

Before and after dialysis and at each dialysis session until the end of the study period

Method of measurement

Using a digital device

5

Description

Respiratory rate

Timepoint

Before and after dialysis and at each dialysis session until the end of the study period

Method of measurement

Using an examination by a researcher

6

Description

Temperature

Timepoint

Before and after dialysis and at each dialysis session until the end of the study period

Method of measurement

Using a digital device

7

Description

O2 Saturation

Timepoint

Before and after dialysis and at each dialysis session until the end of the study period

Method of measurement

Using a digital device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with chronic renal failure with at least three months of hemodialysis undergo exercise for thirty minutes in two 15-minute phases during the first two hours of dialysis. The activity is performed using a pedal that is installed at the bottom of the patient's bed. There is an interval of fifteen minutes for rest during activity. Before the intervention, participants warm up for five minutes and then slowly cool off by pedaling. The pedaling intensity will be such

that the patient reaches a 10% increase in pulse rate compared to the pulse rate before starting the activity. The safe range of pulse rate in patients at the time of activity is considered to be a minimum of 50 and a maximum of 125 beats per minute.

Category

Rehabilitation

2

Description

Control group: Patients with chronic renal failure with at least three months of hemodialysis will undergo 4-hour routine dialysis.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bushehr Shohadaye Khalige Fars Hospital

Full name of responsible person

Mahmoud Mohamadizadeh; student of master degree

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Taleghani Ave.

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Khamisipour

Street address

Vice chancellor for research, Bushehr University of Medical Sciences, Rishahr avenue, Sabzabad avenue

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Boushehr 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**

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Shahnaz Pooladi

Position

Head of the Bushehr Nursing Faculty

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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