Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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<3.5Meq/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)

Phone
+98 917 374 0061

Email address
sh.pooladi@bpums.ac.ir

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
Province
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

Tempreture

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

Street address

Taleghani Ave.

City

Bushehr

Province

Boushehr

Postal code

7434159614

Phone

+98 77 3345 5374

Fax

+98 77 3345 5379

Email

mahmoud.2580@yahoo.com

2

Recruitment center

Name of recruitment center

Salman Farsi hospital

Full name of responsible person

Mahmoud Mohamadizadeh; student of master degree

Street address

Sazabad Ave.

City

Bushehr

Province

Boushehr

Postal code

7518759416

Phone

+98 77 3344 2815

Fax

+98 77 3344 2829

Email

mahmoud.2580@yahoo.com

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, Rishehr avenue, Sabzabad avenue

City
Bushehr

Province
Boushehr

Postal code
7518759577

Phone
+98 77 3345 0178

Email
mahmoud.2580@yahoo.com

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

Street address
Sabzabad avenue

City
Bushehr

Province
Boushehr

Postal code
7518759577

Phone
+98 77 3345 0187

Email
pouladi2008@yahoo.com

Person responsible for scientific 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

Street address
School of nursing and midwifery, Bushehr University of medical sciences, Rishehr avenue, Sabzabad avenue

City
Bushehr

Province
Boushehr

Postal code
7518759577

Phone
+98 77 3345 0187

Email
pouladi2008@yahoo.com

Person responsible for updating data

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
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Street address
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City
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Province
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Postal code
7518759577

Phone
+98 77 3345 0187

Email
Pouladi2008@yahoo.com

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