Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

The effect of Otago exercise on improving motor balance and functional status of hemodialysis patients

Protocol summary

Study aim

Determining The effect of Otago exercise on balance and fanctional status in hemodialysis pateints

Design

Randomized clinical trial with control and interventional group, available sampling

Settings and conduct

- All patients undergoing hemodialysis, Imam Ali Bojnourd Hospital -Accidental allocation of patients in couple of days in two shifts in the morning and evening to the intervention group and patients from odd days to control group to prevent contamination of the groups together - Exercise Otago for eight weeks - Measurement of motor balance, functional status before intervention, eight weeks and three months after training in both intervention and control groups

Participants/Inclusion and exclusion criteria

Entry requirements : Chronic Kidney Disease, no history of falls, age range of 18to 75years, three sessions per week dialysis, hemodialysis history for at least 1 year, Adequacy of dialysis equal to 1.2 or higher, hemoglobin higher than 10 g / dL, person's ability to walk, no exist Musculoskeletal problems Exit requirements: Unwillingness to continue the study, disconnect with the researcher, kidney transplantation, incidence of any heart disease during the study, increased blood pressure, stopping more than three continuous sessions, patient death

Intervention groups

For the intervention group, Otago sports will be taught. This program includes retraining power and balance with walking. This program lasts three times a week and lasts about 30 minutes each time & send to walking two times per week. After training, Otago sports exercises continuously at home (no dialysis day) Is done in a period of 8 weeks. During the whole period of the study, the control group will continue to function normally.

Main outcome variables

-Improve motor function and motor balance in patients undergoing hemodialysis -Supporting hemodialysis patients for independence in everyday activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039320N1**
Registration date: **2018-05-18, 1397/02/28**
Registration timing: **prospective**

Last update: **2018-05-18, 1397/02/28**
Update count: **0**

Registration date

2018-05-18, 1397/02/28

Registrant information

Name

Zahra Ghorbanalinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3225 2040

Email address

z-ghorbanalinejad@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Otago exercise on improving motor balance and functional status of hemodialysis patients

Public title
The effect of Otago exercise in balance and fanctional status

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Have chronic kidney dis (CKD) Not having a history of collapse has caused serious damage in the past Age range (aged 75-89) Perform three sessions per week for dialysis Having a history of hemodialysis for at least 1 year Adequacy of dialysis= 1.2 or higher Hemoglobin level higher than 10 g / dl The ability of a person to walk with or without a crutch and no need for moving aids for eaxample walker and wheelchair Lack of musculoskeletal problems in the lower extremities, such as significant muscle weakness, severe arthritis, history of hip fracture, which exercise obstacles Residence in Bojnord Access and ability to use a cell phone and telegram by the patient or caregiver to provide educational communication and reminder to the patient to perform OTAGO at home

Exclusion criteria:
Unwillingness to continue participating in the study Disconnect with the researcher Performing a kidney transplant The occurrence of any type of heart disease during the study that requires absolute rest and is inconsistent with exercise exercises Un control of the patient's blood pressure Traveling to nearby cities to continue treatment or leave your home for more than a week A patient that stops more than three sessions continuous (one week) Patient's death

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, individual, based on package insert Patients that come to dialysis in morning & afternoon couple days randomized to intervention group and Patients that come to dialysis in morning & afternoon odd days randomized to control group

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Keshavarz Blvd.Tehran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2018-04-13, 1397/01/24

Ethics committee reference number
IR.TUMS.FNM.REC.1397.4948

Health conditions studied

1

Description of health condition studied
Patient undergoing hemodialysis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Balance Score in the tests used in the research

Timepoint
Measurement of motor balance at the beginning of the study(Before the intervention begins)،2 months after the intervention،3 months after the completion of the Otago exercise

Method of measurement
Berg Balance Scale ،Four-Stage Balance Test،Katz Index of Independence in Activities of Daily Living

2

Description
Functional status Score in the tests used in the research

Timepoint
Measurement of fanctional status at the beginning of the study(Before the intervention begins)،2 months after the intervention،3 months after the completion of the Otago

exercise

Method of measurement

Berg Balance Scale ،Four-Stage Balance Test،Katz Index of Independence in Activities of Daily Living

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

2

Description

Control group:

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Zahra Ghorbanalinejad

Street address

Doctor Hesabi Ave., Imam Ali Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology of Tehran University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Ghorbanalinejad

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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