Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Eight Weeks of Intradialytic Combined Resistance and Aerobic Exercise on Quality of Life and Related Factors in Hemodialysis Children.

Protocol summary

Study aim
Investigating The Effect of Intradialytic Combined Resistance and Aerobic Exercise on Quality of Life and Related Factors in Hemodialysis Children.

Design
This is a pre-test and post-test study without a control group. All participants will engage in exercise during dialysis.

Settings and conduct
Exercises will be conducted in the hemodialysis unit of Mofid Children's Hospital under the supervision of nephrologists, rehabilitation specialists, and exercise physiologists. Exercises will include resistance training with weights and pedaling using pedals attached to the dialysis chair during the initiation of dialysis and while the child is connected to the hemodialysis machine.

Participants/Inclusion and exclusion criteria
Inclusion criteria the research: Minimum two months of dialysis history No history of ischemic heart disease or pulmonary diseases No musculoskeletal disorders that would prevent exercise Children aged 8 to 18 years with a stable disease condition At least two dialysis sessions per week Exclusion criteria from the research: Inability to perform exercise Shortness of breath during exercise Any heart or lung disease

Intervention groups
Resistance training includes 3 exercises with 10 repetitions using dumbbells or resistance bands, and aerobic training using pedals that can be attached to the dialysis chair. Exercises will be performed during the first 30 minutes of dialysis.

Main outcome variables
Quality of Life؛ Dialysis Adequacy؛ Blood Electrolytes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241012063340N1**
Registration date: **2024-10-29, 1403/08/08**
Registration timing: **retrospective**

Last update: **2024-10-29, 1403/08/08**
Update count: **0**

Registration date
2024-10-29, 1403/08/08

Registrant information

Name
Reza Ghorbani khosroshahi

Name of organization / entity
The University of Tehran

Country
Iran (Islamic Republic of)

Phone
+98 21 2285 8277

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rghorbani.kh98@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2024-10-21, 1403/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect of Eight Weeks of Intradialytic Combined Resistance and Aerobic Exercise on Quality of Life and Related Factors in Hemodialysis Children.

Public title
Investigating the Effect of Intradialytic Exercise in Children
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Minimum two months of hemodialysis history No history of ischemic heart disease or pulmonary diseases No musculoskeletal disorders that would prevent exercise Children aged 8 to 18 years with a stable disease condition At least two hemodialysis sessions per week
Exclusion criteria:
Inability to perform exercise Shortness of breath during exercise Any heart or lung disease
Age
From **8 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **8**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Sport Sciences and Health, University of Tehran
Street address
Jalal Al-e Ahmad intersection., Northern Karger Street
City
Tehran
Province
Tehran
Postal code
1439813117
Approval date
2024-08-11, 1403/05/21
Ethics committee reference number
IR.UT.SPORT.REC.1403.058

Health conditions studied

1

Description of health condition studied
Chronic Kidney Disease
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Quality Of Life
Timepoint
Before the start of the first training session and after eight weeks at the end of the 24th session
Method of measurement
PedsQL questionnaire

Secondary outcomes

1

Description
Dialysis Adequacy
Timepoint
Before the start of the first training session and after eight weeks at the end of the 24th session
Method of measurement
Dialysis Adequacy Formula

2

Description
Blood Electrolytes
Timepoint
Before the start of the first training session and after eight weeks at the end of the 24th session
Method of measurement
Blood Test

Intervention groups

1

Description
Intervention group: Investigating the effect of exercise, including resistance training for the upper body using weights and aerobic training for the lower body using pedals.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Mofid Children's hospital
Full name of responsible person
Masoumeh Mohkam
Street address
Shariati Street
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1546815514
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Tehran
Full name of responsible person
Mohammadreza Kordi
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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
Tehran University

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
The University of Tehran
Full name of responsible person
Reza Ghorbani khosroshahi
Position
Master Student
Latest degree
Master
Other areas of specialty/work
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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