Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intra-dialytic active and passive exercise on dialysis adequacy and complications

Protocol summary

Summary

The main objective of this clinical trial is to compare the effect of passive and active exercise during dialysis on the adequacy and complications of hemo-dialysis. The inclusion criteria includes the age between 15 and 70 years old, hemo-dialysis for at least 3 months and negative history of cardiovascular disease. The patients that show arrhythmia during exercise will be excluded from the study. The patients referring to the Akhavn hospital in Kashan city will be recruited to this study. The 40 patients will be randomly divided into the active and passive exercise grops. The study methods will be described for patients. Both groups will be done dialysis by filter High Flux,Blood flow velocity 350 cc per minute, Dialysis solution velocity 500 cc per minute for 8 weeks. Exercise will be started of the week 9 and will be continued until week 16. Active group will be done exercise by pedaling minibike for 60 minutes within the first two hours of dialysis. The exercise sessions will be divided to 10 minutes of exercise and 10 minutes of rest. Passive group will be done exercise by the electronic minibike in the same manner. Blood pressure will be measured at the beginning and the end of each hour of dialysis.The adequacy of dialysis, phosphorus, calcium, sodium and potassium will be measured at the end of 8 and 16weeks and will be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210316228N4**
Registration date: **2012-11-26, 1391/09/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-11-26, 1391/09/06

Registrant information

Name
Negin Masoudi Alavi
Name of organization / entity
Kashan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-08-21, 1392/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intra-dialytic active and passive exercise on dialysis adequacy and complications

Public title

The effect of active and passive exercise on dialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The age between 15 to 70 years old; treated with hemodialysis for more than three months; treated by hemodialysis three times per week for at least

4 hours in every session; Negative history of cardiovascular disease; Negative history of myocardial infarction in previous 6 months; Negative history of stroke; Negative history of chronic pulmonary disease; Negative history of musculoskeletal disease and autoimmune diseases. Exclusion criteria: The cardiac arrhythmia during exercise which need anti-arrhythmia drugs; the poor corporation of the patient; experiencing any problem during exercise.

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kashan University of Medical Sciences

Street address
Kashan University of Medical Sciences, Ghotb Ravandi Highway

City
Kashan

Postal code
8715981151

Approval date
2012-07-26, 1391/05/05

Ethics committee reference number
1910/1/5/29/پ

Health conditions studied

1

Description of health condition studied
dialysis

ICD-10 code
Y84.1

ICD-10 code description
Kidney dialysis

Primary outcomes

1

Description
Blood pressure

Timepoint
beggining of the study and final per hour of hemodialysis

Method of measurement
blood pressure measurement cuff

2

Description
Calcium

Timepoint
beginning of the study

Method of measurement
blood electrolytes analysis

3

Description
phosphoros

Timepoint
beginning of the study

Method of measurement
blood electrolytes analysis

4

Description
potassium

Timepoint
beginning of the study

Method of measurement
blood electrolytes analysis

5

Description
sodium

Timepoint
beginning of the study

Method of measurement
blood electrolytes analysis

6

Description
adequacy of dialysis

Timepoint
beginning of the study

Method of measurement
adequacy of dialysis formula

Secondary outcomes

empty

Intervention groups

1

Description
Active exercise by pedaling a mini bike for 1 hour in 10 minutes intervals during the beginning two hours of the hemodialysis
Category
Treatment - Other

2

Description
Passive exercise with electronic bike for 1 hour in 10 minutes intervals during the beginning two hours of the hemodialysis
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhavan Hospital
Full name of responsible person
Zahra sadat Mosavian
Street address
Panzdah Khordad Square, Akhavan Hospital
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Negin Masoudi Alavi
Street address
Ghotb Ravandi Highway, Kashan University of Medical Sciences
City
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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
Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Faculty Member
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty