

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

2012-11-26, 1391/09/06

#### 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 groups. 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 16 weeks and will be compared between groups.

#### Registrant information

##### Name

Negin Masoudi Alavi

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 36 1555 0021

##### Email address

masudialavi\_n@kaums.ac.ir

#### 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

#### 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

#### 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**

beginning 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

Kashan

### 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

Kashan University of Medical Sciences

#### Full name of responsible person

Negin Masoudi Alavi

#### Position

Faculty member

#### Other areas of specialty/work

#### Street address

Ghotb Ravandi Highway, Kashan University of Medical Sciences

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#### Postal code

#### Phone

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#### Email

masudialavi\_N@kaums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Position

Ph.D

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

#### Name of organization / entity

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#### Position

Faculty Member

#### Other areas of specialty/work

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**Web page address****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*