

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of eight weeks of isometric resistance training and branched-chain amino acids supplementation on muscle capacity and serum albumin levels in hemodialysis patients

#### Protocol summary

##### Summary

The aim of this study was to evaluate the effect of eight weeks of isometric training intradialytic and branched-chain amino acids (BCAA) supplementation on muscle capacity and serum albumin in hemodialysis patients. The statistical population was the hemodialysis patients in Tehran and the sample population was patients in dialysis ward of Baqiyatallah hospital. In a clinical trial based on the inclusion and exclusion criteria 51 patients were randomly allocated into three groups: exercise group (EX) (n=17), exercise and BCAA group (EXBCAA) (n=17) and control group (n=17). In EXBCAA group, with the supervision of a nutritionist and a nephrologist 6 grams of BCAA were given to patients daily and training program was done 3 times a week for 2 months (24 sessions). Forearm endurance, leg raise endurance, and grip strength were measured for muscle capacity aspect and serum albumin levels were evaluated test before and post-intervention. Inclusion criteria: patients between ages of 18-80; patients who have undergone hemodialysis for a minimum of 6 months exclusion criteria: cancer; nephrotic syndrome; type B hepatitis; type C hepatitis or active infection during the previous 4 months

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017101014998N2**

Registration date: **2017-11-17, 1396/08/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-17, 1396/08/26

#### Registrant information

##### Name

Ali Tayebi

##### Name of organization / entity

Baqiyatallah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 105 8516

##### Email address

tayebi@bmsu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Baqiyatallah Azam University of Medical Sciences, nephrology and urology research center

#### Expected recruitment start date

2017-04-09, 1396/01/20

#### Expected recruitment end date

2017-04-21, 1396/02/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of eight weeks of isometric resistance training and branched-chain amino acids supplementation on muscle capacity and serum albumin levels in hemodialysis patients

#### Public title

effect of exercise and dietary supplement in hemodialysis patients

#### Purpose

Supportive

## **Inclusion/Exclusion criteria**

inclusion criteria: patients between ages of 18-80; patients who have undergone hemodialysis for a minimum of 6 months exclusion criteria: cancer; nephrotic syndrome; type B hepatitis; type C hepatitis or active infection during the previous 4 months; dementia; neurologic disease; no severe cardiovascular problem; no severe infections; no chronic liver disease; no chronic disease with unknown origin

## **Age**

From **18 years** old to **80 years** old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **51**

## **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**

Sports Sciences Research Institute of Iran

##### **Street address**

No. 3, 5th Alley, Miremad Street, Motahhari Street,

##### **City**

Tehran

##### **Postal code**

1587958711

#### **Approval date**

2017-08-30, 1396/06/08

#### **Ethics committee reference number**

IR.SSRI.REC.1396.127

## **Health conditions studied**

### 1

#### **Description of health condition studied**

end stage renal failure

#### **ICD-10 code**

I12

## **ICD-10 code description**

Hypertensive renal disease with renal failure

## **Primary outcomes**

### 1

#### **Description**

muscle capacity

#### **Timepoint**

pre and post intervention

#### **Method of measurement**

grip strength measured by hydraulic dynamometer.  
endurance with chronometer

### 2

#### **Description**

albumin serum levels

#### **Timepoint**

pre and post intervention

#### **Method of measurement**

blood test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

exercise and BCAA group: intradialytic isometric resistance training and supplementation with 6 grams of BCAA

#### **Category**

Rehabilitation

### 2

#### **Description**

exercise group : intradialytic isometric resistance training .

#### **Category**

Rehabilitation

### 3

#### **Description**

control group : routine treatment with hemodialysis with no intervention

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Baqiyatallah azam hospital

**Full name of responsible person**  
**Street address**  
mollasadra street, tehran, iran  
**City**  
tehran

**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 8126 2073  
**Fax**  
**Email**  
tayybi.ali@gmail.com  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Baqiyatallah Azam University of Medical Sciences  
nephrology and urology center  
**Full name of responsible person**  
Ali Tayebi  
**Street address**  
nephrology and urology research center, ground floor,  
Baqiyatallah hospital, Mollasadra street  
**City**  
tehran  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Baqiyatallah Azam University of Medical Sciences  
nephrology and urology center  
**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**  
nephrology and urology research center, nursing  
faculty of Baqiyatallah University of Medical Scienc  
**Full name of responsible person**  
Ali Tayebi  
**Position**  
PhD candidate, faculty member  
**Other areas of specialty/work**  
**Street address**  
baqiyatallah university of medical sciences,  
Mollasadra

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
nephrology and urology research center, nursing  
faculty of Baqiyatallah University of Medical Scienc  
**Full name of responsible person**  
Ali Tayebi  
**Position**  
phD candidate  
**Other areas of specialty/work**  
**Street address**  
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Tehran  
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+98 21 8126 2073  
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tayybi.ali@gmail.com  
**Web page address**

## Person responsible for updating data

#### Contact

## 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*