

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Investigating the effect of high protein oral nutritional supplement on dialysis adequacy in hemodialysis patients

#### Protocol summary

##### Summary

In a clinical trial study, 44 hemodialysis patients who were qualified to enter the research were selected and allocated randomly in two groups: an intervention group (n=22) and a control group (n=22). The present study aims to investigate the effects of high protein oral nutritional supplements on dialysis adequacy. Patients in hemodialysis ward of Baqiyatallah Azam Hospital were informed about the research and filled out a written consent. In intervention group, as prescribed and controlled by nutritionists and nephrologists, a cup (24 gr) of Iso-Whey protein powder from pharmaceutical company as well as Karen nutritional-critical supplements were used for two months on daily basis. For both groups, before intervention and one and two months after intervention dialysis adequacy was measured based on URR and Kt/V along with a series of laboratory parameters as well as investigation of nutritional status according to mental comprehensive assessment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201209088650N5**

Registration date: **2015-01-15, 1393/10/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-01-15, 1393/10/25

##### Registrant information

##### Name

Abbas Ebadi

##### Name of organization / entity

Baqiyatallah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2228 6057

##### Email address

ebadi1347@bmsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Nursing Faculty, Baqiyatallah University of Medical Sciences Nephrology and Urology Research Center, Baqiyatallah University of Medical Sciences Exercise Physiology Research Center, Baqiyatallah University of Medical Sciences Nutrition Research Center, Baqiyatallah University of Medical Sciences,

##### Expected recruitment start date

2014-08-23, 1393/06/01

##### Expected recruitment end date

2014-11-06, 1393/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of high protein oral nutritional supplement on dialysis adequacy in hemodialysis patients

##### Public title

Effect of nutritional supplementation on dialysis adequate

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria: Written informed consent to participate in research Albumin less than 4 g per deciliter before the

study. At least 6 months have been treated with hemodialysis. Older than 18 and younger than 75 years Hemodialysis: two or more times per week 35kg/m2 >BMI> 18.5 kg / m2 Absence of acute infection Absence of heart failure or severe respiratory Absence of chronic inflammatory disease with unknown sources Not using immunosuppressive drugs Absence of parenteral nutrition Absence of recent surgery or during follow up over the past three months. Absence of chronic liver disease Absence of nephritic syndrome Absence of cancer, dementia, Neurological Disease Absence of hepatitis B, hepatitis C, HIV, infection in the last 4 weeks Exclusion criteria: Allergic complications caused by oral nutritional supplements Confirmation of any problems that the inclusion criteria listed during the study.

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **44**

#### 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

The ethics committee of the Baqiyatallah University of Medical Sciences

##### Street address

sheykh bahayi St, mollasadra Ave, vanak Squ.

##### City

Tehran

##### Postal code

#### Approval date

2014-11-02, 1393/08/11

#### Ethics committee reference number

5904/5/340

## Health conditions studied

### 1

#### Description of health condition studied

hemodialysis

#### ICD-10 code

Z49.1

#### ICD-10 code description

Extracorporeal dialysis

## Primary outcomes

### 1

#### Description

Dialysis adequacy

#### Timepoint

Baseline, one month after the start of intervention, two months after the intervention.

#### Method of measurement

Daugirddasll

### 2

#### Description

Dialysis adequacy

#### Timepoint

Baseline, one month after the start of intervention, two months after the intervention.

#### Method of measurement

URR=BUN1-BUN2/BUN1

## Secondary outcomes

### 1

#### Description

Albumin

#### Timepoint

Baseline, one month after the start of intervention, two months after the intervention.

#### Method of measurement

Blood tests

### 2

#### Description

Total Iron Binding Capacity

#### Timepoint

Baseline, one month after the start of intervention, two months after the intervention.

#### Method of measurement

Blood tests

### 3

#### Description

Blood Urea Nitrogen

#### Timepoint

Baseline, one month after the start of intervention, two months after the intervention.

#### Method of measurement

Blood tests

#### 4

**Description**

Calcium

**Timepoint**

Baseline, one month after the start of intervention, two months after the intervention.

**Method of measurement**

Blood tests

#### 5

**Description**

Phosphorus

**Timepoint**

Baseline, one month after the start of intervention, two months after the intervention.

**Method of measurement**

Blood tests

#### 6

**Description**

Creatinine

**Timepoint**

Baseline, one month after the start of intervention, two months after the intervention.

**Method of measurement**

Blood tests

#### 7

**Description**

Sodium

**Timepoint**

Baseline, one month after the start of intervention, two months after the intervention.

**Method of measurement**

Blood tests

#### 8

**Description**

Potassium

**Timepoint**

Baseline, one month after the start of intervention, two months after the intervention.

**Method of measurement**

Blood tests

### Intervention groups

#### 1

**Description**

Intervention group: Isowhey oral nutritional supplement daily - a cup (24 grams) for two months.

**Category**

Prevention

#### 2

**Description**

Control group: No action

**Category**

Prevention

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Baqiyatallah Hospital

**Full name of responsible person****Street address****City**

Tehran

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Vice Chancellor for research of Nursing Faculty,  
Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Dr Ali Rahmani

**Street address**

Baqiyatallah University of Medical Sciences,Sheykh  
Bahayi St, Mollasadra Ave, Vanak Squ, Tehran, Iran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Nursing Faculty,  
Baqiyatallah University of Medical Sciences

**Proportion provided by this source****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*

#### 2

**Sponsor****Name of organization / entity**

Exercise Physiology Research Center, Baqiyatallah  
University of Medical Sciences,

**Full name of responsible person**

Dr Vahid Sobhani

**Street address**

Baqiyatallah University of Medical Sciences,Sheykh  
Bahayi St, Mollasadra Ave, Vanak Squ, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Exercise Physiology Research Center, Baqiyatallah University of Medical Sciences,

**Proportion provided by this source**

**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*

**3**

**Sponsor**

**Name of organization / entity**

Nephrology and Urology Research Center, Baqiyatallah University of Medical Sciences,

**Full name of responsible person**

Dr Behzad Einollahi

**Street address**

Baqiyatallah University of Medical Sciences, Sheykh Bahayi St, Mollasadra Ave, Vanak Squ, , Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Nephrology and Urology Research Center, Baqiyatallah University of Medical Sciences,

**Proportion provided by this source**

**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*

**4**

**Sponsor**

**Name of organization / entity**

Nutrition Research Center, Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Samadi

**Street address**

Baqiyatallah University of Medical Sciences, Sheykh Bahayi St, Mollasadra Ave, Vanak Squ, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Nutrition Research Center, Baqiyatallah University of Medical Sciences

**Proportion provided by this source**

**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**

Nursing Faculty, Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Effat Afaghi

**Position**

MSc student

**Other areas of specialty/work**

**Street address**

Nursing Faculty, Baqiyatallah University of Medical Sciences

**City**

Tehran

**Postal code**

**Phone**

+98 21 2288 9941

**Fax**

**Email**

effat.afaghi@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Nursing Faculty, Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Dr Abbas Ebadi

**Position**

PhD in Nursing Education

**Other areas of specialty/work**

**Street address**

Nursing Faculty, Baqiyatallah University of Medical Sciences

**City**

tehran

**Postal code**

**Phone**

+98 21 2288 9941

**Fax**

**Email**

ebadi1347@bmsu.sc.ir

**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*