

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)

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+98 21 2228 6057

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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

DaugirddasII

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

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Person responsible for scientific inquiries

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PhD in Nursing Education

Other areas of specialty/work

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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