Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 2026

The effect of magnesium and creatine co-supplementation on malnutrition, quality of life and hand grip strengh in hemodialysis patients

Protocol summary

Study aim
To determine and compare serum albumin, fatigue, hand grip strength, and quality of life levels in hemodialysis patients receiving magnesium-creatine supplementation versus placebo, At baseline and after 12 weeks

Design
A phase 3, double-blind, parallel RCT on 70 patients, with allocation into two groups via sealed envelope.

Settings and conduct
will be conducted starting in fall (1405) at Hojjatieh, Zahra-ye Marzieh, Farabi, and Amin hospitals in Isfahan. Participants will then be allocated into two groups using stratified randomization based on BMI, with an assigned code via the sealed envelope website. The intervention will receive a daily magnesium oxide and creatine supplement, while the control will receive a daily packet containing dextrose and starch, visually similar in appearance to the magnesium-creatine supplement. None of the individuals involved in the intervention process are aware of the group assignments.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: On hemodialysis for ≥3 months Dialysis ≥ 3 times/week mg < 1.5 mmol/L Not enrolled in another study Not pregnant or breastfeeding No cancer, advanced liver disease, bipolar disorder, or heart failure No recent (past month) use/dose change of drugs/supplements affecting outcomes (e.g., L-carnitine, protein supplements, albumin, nutritional supplements) No enteral/parenteral nutrition Age ≥18 Not a kidney transplant candidate Exclusion Criteria: Change in dialysis type Onset of cachexia-causing illness (e.g., cancer, AIDS, Kidney transplant) Use of drugs/supplements affecting outcomes In the event of adverse effects occurring, and if the individual is unwilling to continue with the intervention

Intervention groups
Intervention: 200 mg magnesium oxide, 2 g creatine, and 1 g dextrose Control: 1 g dextrose and 2 g starch.

Main outcome variables
serum albumin, fatigue, hand grip strength, and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130903014551N15**
Registration date: **2026-08-07, 1405/05/16**
Registration timing: **prospective**

Last update: **2026-08-07, 1405/05/16**
Update count: **0**

Registration date
2026-08-07, 1405/05/16

Registrant information

Name
Mohammad Hossein Rouhani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-06, 1405/06/15

Expected recruitment end date
2027-05-05, 1406/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of magnesium and creatine co-supplementation on malnutrition, quality of life and hand grip strengh in hemodialysis patients

Public title

The effect of magnesium and creatine co-supplementation on malnutrition, quality of life and hand grip strengh in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have been undergoing hemodialysis treatment for at least 3 months. Undergo dialysis 3 times per week. Not have hypermagnesemia (Mg > 1.5 mmol/L) Not be enrolled in any other study. Not be pregnant or breastfeeding. Not have other diseases such as cancer, advanced liver disease, bipolar disorder, or heart failure. Not be taking medications or supplements that affect the dependent variables — such as L-carnitine, protein supplements, albumin vials, or any type of nutritional supplement — that they started or changed the dosage of within the past month. Not be receiving enteral or parenteral nutrition. Be 18 years of age or older. Not be a candidate for kidney transplant surgery.

Exclusion criteria:

Change in the type of dialysis. Development of diseases that lead to cachexia and loss of muscle mass, such as cancer, AIDS and Kidney transplantation Use of medications or supplements affecting the dependent variables. If the individual shows adverse effects related to the supplement, the adverse event will be reported, and if the individual is unwilling to continue the intervention, they will be withdrawn from the study.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the code assigned to each individual, participants will be randomly divided into intervention and control groups using stratified randomization based on BMI (25<BMI<18.5 and BMI≥25) via the sealed envelope website. To conceal the random allocation, opaque envelopes sealed with a random sequence will be used. In this method, after generating the random sequence, a number of opaque envelopes corresponding to the study's sample size will be prepared, and each of the generated random sequences will be recorded on a card; the cards will then be placed inside the envelopes in order. To preserve the random sequence, the outer surface of the envelopes will be numbered in the same order. Finally, the envelopes will be sealed and, separated by BMI classification, placed in order inside boxes. At the start of participant enrollment, based on the order in which eligible participants enter the study, the envelopes will be opened sequentially, revealing the assigned group for that participant.

Blinding (investigator's opinion)

Triple blinded

Blinding description

All steps of randomization and allocation concealment will be carried out by a third party. The intervention group will receive one daily packet of supplement containing 200 mg of magnesium oxide, 2 g of creatine, and 1 g of dextrose (to improve taste), while the control group will receive one daily packet containing 1 g of dextrose and 2 g of starch, which will be visually similar in appearance to the magnesium-creatine supplement used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2026-08-02, 1405/05/11

Ethics committee reference number

IR.MUI.MED.REC.1405.186

Health conditions studied

1

Description of health condition studied
Chronic Kidney Disease (CKD) Requiring Hemodialysis
ICD-10 code
Dependence
ICD-10 code description
Z99.2

Primary outcomes

1

Description
Serum albumin
Timepoint
Measurement of serum albumin before the intervention begins and at the end of the twelfth week
Method of measurement
Blood sample and using the Bromocresol Green method

2

Description
En Fatigue levels
Timepoint
Measurement of fatigue levels before the intervention begins and at the end of the twelfth week
Method of measurement
پرسشنامه MFI-20

3

Description
Handgrip strength
Timepoint
Measurement of handgrip strength before the intervention begins and at the end of the twelfth week
Method of measurement
En Based on the Southampton method using the handgrip device (SH5002 SAEHAN Spring)

4

Description
Quality of life levels
Timepoint
Measurement of quality of life levels before the intervention begins and at the end of the twelfth week
Method of measurement
Kidney Disease Quality of Life Questionnaire (KDQOL)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The intervention group will receive one daily packet of supplement containing 200 mg magnesium oxide, 2 g creatine, and 1 g dextrose (to improve taste), The supplements used in the intervention and placebo groups will be prepared in identical sachet form. The supplement/placebo will be taken once daily after breakfast, and on dialysis days, intake will be scheduled after the first meal following the dialysis session. The study duration will be 12 weeks. To assess adherence, patients will be met with and monitored weekly, with each visit lasting 20 minutes. Every two weeks, supplements/placebo for the next 14 days will be given to participants, and the empty packets from the previous period will be collected. Patients will also be contacted via social media/messaging platforms. Additionally, a checklist will be given to patients to mark each time they take the supplement or placebo. However, to assess dietary intake — a confounding factor in this study — six 24-hour dietary recalls will be used. One dietary recall will be taken at the beginning of the study, before the intervention begins. The remaining six dietary recalls will be taken at weeks 2, 4, 6, 8, 10, and 12, divided into 4 regular days and 2 dialysis days. Participants will be asked not to change their diet. Patients in both groups will receive a list of dietary recommendations relevant to hemodialysis patients. Serum albumin levels, fatigue, muscle mass and function, quality of life, will be measured at the beginning and end of the study.
Category
Treatment - Other

2

Description
Control group: The supplements used in the intervention and placebo groups will be prepared in identical sachet form. The supplement/placebo will be taken once daily after breakfast, and on dialysis days, intake will be scheduled after the first meal following the dialysis session. The study duration will be 12 weeks. To assess adherence, patients will be met with and monitored weekly, with each visit lasting 20 minutes. Every two weeks, supplements/placebo for the next 14 days will be given to participants, and the empty packets from the previous period will be collected. Patients will also be contacted via social media/messaging platforms. Additionally, a checklist will be given to patients to mark each time they take the supplement or placebo. However, to assess dietary intake — a confounding factor in this study — six 24-hour dietary recalls will be used. One dietary recall will be taken at the beginning of the study, before the intervention begins. The remaining six dietary recalls will be taken at weeks 2, 4, 6, 8, 10, and 12, divided into 4 regular days and 2 dialysis days. Participants will be asked not to change their diet. Patients in both groups will receive a list of dietary recommendations relevant to hemodialysis patients. Serum albumin levels, fatigue, muscle mass and function, quality of life, will be measured at the

beginning and end of the study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hojjatieh Hospital

Full name of responsible person

Dr. Mojgan Mortazavi

Street address

Isfahan, Imam Sajad (A.S.) Street, Sepah Salar Street, across from Sepah Bank, Hojatieh Hospital.

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Email

info@hojjat-hospital.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Askari@mui.ac.ir

Web page address

https://research.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Hossein Rouhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available