

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of Global Diet Quality Score (GDQS) compared to the control diet (diet for hemodialysis patients) on the levels of creatinine (Cr), blood urea nitrogen (BUN) and serum electrolytes in individuals with chronic kidney disease under hemodialysis: A randomized clinical trial study

Protocol summary

Study aim

Determining the effect of diet based on the Global Diet Quality Score (GDQS) compared to the control diet (the diet of hemodialysis patients) on the levels of creatinine (Cr), blood urea nitrogen (BUN) and serum electrolytes in people with chronic diseases Kidney under hemodialysis: a randomized clinical trial study

Design

A randomized, parallel, controlled clinical trial. The number of 50 eligible participants to participate in the study will be divided into one of 2 intervention and control groups (n=25) using a simple randomization method

Settings and conduct

This study will be done in Shahid Rahmonun and Goodarz Hospital, Yazd. A total of 50 eligible people will be randomly assigned to 2 groups for 3 months to receive GDQS or standard dietary recommendations. At the beginning of the study and after 3 months from the start of the study, creatinine, blood urea nitrogen, serum electrolytes will be evaluated. Due to the nature of the study, blinding was not done.

Participants/Inclusion and exclusion criteria

Adults with the age range of 18 to 70 years and undergoing hemodialysis treatment (at least 2 times a week) for at least 1 months and more who complete the consent form to enter the study. Exclusion criteria: pregnant and lactating women, people with a history of Cancer, liver disease, cognitive or psychological disorder, immunodeficiency, AIDS and severe inflammatory disease.

Intervention groups

Individuals will receive the GDQS diet. Participants will learn the GDQS diet in 12 face-to-face sessions. They will

also receive GDQS dietary advice during the course.

Control group: subjects will receive standard diet.

Participants will be taught the standard diet in 12 face-to-face sessions. They will also receive standard dietary advice throughout the course. The duration of intervention and study will be 3 months

Main outcome variables

creatinine, blood urea nitrogen, serum electrolytes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210427051098N5**

Registration date: **2023-12-11, 1402/09/20**

Registration timing: **prospective**

Last update: **2023-12-11, 1402/09/20**

Update count: **0**

Registration date

2023-12-11, 1402/09/20

Registrant information

Name

Sayyed Saeid Khayyatzaheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

Email address

khayyatzaheh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Global Diet Quality Score (GDQS) compared to the control diet (diet for hemodialysis patients) on the levels of creatinine (Cr), blood urea nitrogen (BUN) and serum electrolytes in individuals with chronic kidney disease under hemodialysis: A randomized clinical trial study

Public title

Investigating the effect of diet based on the global diet quality score in hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals under hemodialysis (at least 2 times a week) for at least 1 months or more Completion of informed consent

Exclusion criteria:

History of cancer Suffering from hepatitis Suffering from liver cancer Taking medications for liver disease Having a specific perception or psychological disorder Immunodeficiency AIDS Suffering from a severe inflammatory disease Pregnancy Lactation

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the eligible people and receiving ethical consent, people will be divided into two groups (intervention: GDQS-based diet or control: standard diet) by random allocation method. At first, each person will receive a unique code. Then all the codes will enter the Random Allocation software. Software inputs will include the total number of samples and the number of treatment groups (intervention and control). The output of the software will include random numbers assigned for both groups. The distribution ratio of people will be 1 to 1. Each person has an equal chance to be placed in each of the groups, and the participants cannot predict which

group they will be placed in. Randomization will be done as a block classification based on gender (male and female) and BMI (higher and lower than 25) and in a block with a block size equal to 6.

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

Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Sciences and Health Services Campus- Shohadaye Gomnam Blvd- Alem Square- Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2023-11-25, 1402/09/04

Ethics committee reference number

IR.SSU.SPH.REC.1402.103

Health conditions studied

1

Description of health condition studied

Individuals with chronic kidney disease under hemodialysis

ICD-10 code

I95.3

ICD-10 code description

Hypotension of hemodialysis

Primary outcomes

1

Description

Creatinine

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

2

Description

Blood urea nitrogen (BUN)

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

3

Description

Serum Albumin

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

4

Description

Alkaline phosphatase

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

5

Description

Parathormone

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

6

Description

Total bilirubin

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

7

Description

Direct bilirubin

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

8

Description

Sodium

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

9

Description

Potassium

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

10

Description

Phosphorus

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

11

Description

Calcium

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

12

Description

Fasting Blood Glucose

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

13

Description

Total cholesterol

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

14

Description

Triglyceride

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Pars Azmoun biochemical kit

15

Description

Depression

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Validated hospital anxiety and depression questionnaire

16

Description

Anxiety

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Validated hospital anxiety and depression questionnaire

17

Description

Sleep quality

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Validated Pittsburgh questionnaire

18

Description

Quality of Life

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Validated KDQOL-36 questionnaire

19

Description

Fatigue

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Piper's validated fatigue questionnaire and scale

Secondary outcomes

1

Description

Weight

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Weighting scale

2

Description

Body Mass Index (BMI)

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Body composition analyzer

3

Description

Waist circumference

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Tape measure

4

Description

Hips circumference

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Tape measure

5

Description

Fat mass

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Body composition analyzer

6

Description

Fat free mass

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Body composition analyzer

7

Description

Blood pressure

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Measurement of systolic and diastolic blood pressure (mmHg)

Intervention groups

1

Description

Intervention group: In the GDQS-based diet group, people undergoing hemodialysis treatment will receive GDQS diet training for 12 weeks (one training session per week) and each session will last 10 minutes. The amount of prescribed energy intake for people is calculated according to the Harris-Benedict equation. (22) If the body mass index of people is less than 25, the current weight of people is used to calculate energy; But if the body mass index is more than 25, the adjusted weight of people according to the body mass index of 25 is used to calculate energy. In the control group, the standard diet of hemodialysis patients will be set for the patients and they will be taught by nutrition experts. The GDQS is a completely food-based measure of 25 food groups: 16 healthy food groups, 7 unhealthy food groups, and 2 food groups (red meat, full-fat dairy) that are unhealthy if consumed in excess. For the 24 GDQS food groups, three ranges of intake are defined (in grams per day) and used in scoring the metric: low, moderate, and high. For a food

group (full-fat dairy), four ranges of consumption are used: low, medium, high, and very high. The diet will be adjusted based on the recommendations of GDQS according to the amount of energy needed by the person. In designing this diet, get more dark green leafy vegetables, cabbage family, orange root vegetables (carrots, sweet potatoes, acorns, pumpkins, and pumpkins) and other vegetables, orange fruits (persimmons, apricots, nectarines, cantaloupe and.), citrus fruits and other fruits, legumes, nuts and seeds, poultry meat, lamb and fish, whole grains, liquid oils, low-fat dairy products, and eggs and reducing the intake of root vegetables and white tubers (All kinds of turnips and radishes, yolks and.), processed meats, refined grains and toasted bread, sweets, and drinks sweetened with sugar, ice cream, juices and fried foods and especially high-fat dairy products and red meat are emphasized. In the training sessions, the GDQS dietary recommendations will be fully explained to the individuals. These recommendations will be based on the economic status people's access to food and the status of some other diseases such as digestive diseases. People can communicate with experts through phone calls or messengers during the 12 weeks of intervention.

Category

N/A

2

Description

Control group: In the control group, the standard diet will be designed based on the dietary guidelines of the people undergoing hemodialysis treatment for the people in the control group. The percentage of protein intake will be considered as 1.2 grams per kilogram of people's weight, and after calculating the percentage of protein, the percentage of other macronutrients will also be determined, and based on that, the standard diet will be designed. Individuals can stay in touch with experts through phone calls or messengers during the 12 weeks of intervention. The number of training sessions in the standard diet group will be 12 sessions

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahnamoon Hospital

Full name of responsible person

Sayyed Saeid Khayatzadeh

Street address

Emergency Alley, Shahid Beheshti Square, Farrokhi Street, Yazd Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargouei

Street address

Vice President of Research and Technology of Shahid Sadoughi University of Medical Sciences, Imam Reza Research Educational Complex, Student Blvd, Imam Hossein Square, Yazd City

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Province

Yazd

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891618863

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Email

dvc.research@ssu.ac.ir

Grant name

Dr. Amin Salehi Abargouei/ Vice Chancellor of Research and Technology, Shahid Sadoughi University of Medical Sciences, Yazd

Grant code / Reference number

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

No

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Sara Bagherpour

Position

Master student in nutrition science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Name of organization / entity

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Sara Bagherpour

Position

Master Student in nutrition science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

primary outcome will be available at the end of study

When the data will become available and for how long

From January 2024

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Academic institutes can send their official request to the
email of the scientific director of the project. the data will
be sent after confirmation of ethics committee of shahid
sadoughi university of medical sciences. It is not possible
to perform statistical analysis on the data.

From where data/document is obtainable

Sayyed Saeid Khayyatadeh Assistant professor of
nutrition in Shahid Sadoughi university of medical
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What processes are involved for a request to access data/document

Academic institutes can send their official request to the
email of the scientific director of the project. The data
will be sent after confirmation of ethics committee of
Shahid Sadoughi university of medical sciences

Comments