Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Assessing the effect of energetic water on kidney function in moderate to severe chronic kidney disease (CKD) patients

Protocol summary

Study aim
Assessing the effect of energetic water on kidney function in moderate to severe CKD patients

Design
In this randomized controlled clinical trial, 30 patients are enrolled into two groups, intervention and control groups, using randomized block design method by Random Allocation Software.

Settings and conduct
In the Ghaem Hospital clinic in Mashhad, 30 patients with moderate to severe chronic kidney disease after accepting participation in the study and obtaining informed consent are divided into two groups of control and intervention.The intervention group, in addition to the usual treatments, received 1000 cc of energetic water daily for three months, and the control group received the usual treatments and ordinary water in the same package. Necessary tests and ultrasound of the kidneys will be performed for three months.

Participants/Inclusion and exclusion criteria
People with chronic kidney disease (CKD) are included in the study. Patients with severe disease in other organs such as the heart, lungs, liver are excluded from the study.

Intervention groups
In the intervention group, patients consume one liter of energetic water daily for 3 months in addition to the usual drugs. In the control group, in addition to the usual treatments, they receive ordinary water in similar containers.

Main outcome variables
Blood pressure, serum creatinine, urinary protein, electrolytes, C reactive protein (CRP)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20080916001256N3**
Registration date: **2021-03-14, 1399/12/24**
Registration timing: **prospective**

Last update: **2021-03-14, 1399/12/24**
Update count: **0**

Registration date
2021-03-14, 1399/12/24

Registrant information
Name
Maryam Hami
Name of organization / entity
Health Organization
Country
Iran (Islamic Republic of)
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+98 51 1765 9556
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-10, 1400/01/21
Expected recruitment end date
2021-08-23, 1400/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effect of energetic water on kidney function in moderate to severe chronic kidney disease (CKD) patients

Public title
The effect of energizing water on kidney function in patients with chronic kidney disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Chronic Kidney disease (CKD) patients(moderate to severe) Having informed consent to enter the study
Exclusion criteria:
Uncontrolled Diabetes Mellitus (Hb A1C>7 & Fsting Blood Sugar>130 mg/dl) Uncontrolled hypertension (systolic Blood pressure>160 & diastolic Blood Pressure >100 mmHg) Malignancies Obstructive Uropathy Stage 5 Chronic Kidney disease (CKD) active infection intake of Nephrotoxic drugs severe Congestive Heart Failure (Ejection Fraction<40%) Liver failure (cirrhosis) Poly cystic Kidney disease Pregnancy Renal transplantation Dissatisfaction with continued cooperation Smoking and drugs abuse Breastfeeding Accompanied by acute kidney diseases
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The permuted block technique was used to select patients in each of the treatment and control groups. Random blocks with variable sizes of 4 to 6 with a random sequence of colored leaves are designed in Random Allocation Software and are provided to the secretary in sealed packages.Each block consists of two to three people from the intervention group and two or three people from the control group. For each patient, one of the envelopes will be opened and the sheet on top is handed to the patient. According to the color of the paper, the patient will be categorized in one of the groups and will be registered in the relevant color list.
Blinding (investigator's opinion)
Double blinded
Blinding description
The therapist and the patient do not know the type of the water and for both of them Water should be sent in exactly the same package and in equal volume.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University Of Medical sciences
Street address
Vice President of Research, Ghoreshi building, Daneshgah st.
City
Mashhad
Province
Razavi Khorasan
Postal code
91767-99199
Approval date
2021-01-16, 1399/10/27
Ethics committee reference number
IR.MUMS.REC.1399.560

Health conditions studied

1

Description of health condition studied
Chronic Kidney disease
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Serum Creatinine
Timepoint
0-45-90 days
Method of measurement
Laboratory

2

Description
Serum Lipid
Timepoint
0-45-90 days
Method of measurement
Laboratory

3

Description
Urine Protein
Timepoint

0-45-90 days

Method of measurement

Laboratory

4

Description

Hematuria

Timepoint

0-45-90 days

Method of measurement

Laboratory

Secondary outcomes

1

Description

Serum Uric Acid

Timepoint

0-45-90 days

Method of measurement

Laboratory

2

Description

C-Reactive Protein (CRP)

Timepoint

0-45-90 days

Method of measurement

Laboratory

3

Description

Liver Function test

Timepoint

0-45-90 days

Method of measurement

Laboratory

Intervention groups

1

Description

Intervention group: Patients with moderate to severe CKD (GFR between 15 and 60) who meet the inclusion criteria after obtaining informed consent enter to study. They receive 1000 cc energetic water daily for three months, in addition to the usual treatments. Necessary tests are performed first and before treatment, in the middle of treatment and then at the end of three months. Kidney ultrasound will be performed at the beginning and end of the study.

Category

Treatment - Other

2

Description

Control group: Patients with moderate to severe CKD (GFR between 15 and 60) who meet the inclusion criteria after obtaining informed consent enter to study. They receive 1000 cc normal water daily for three months, in addition to the usual treatments. Necessary tests are performed first and before treatment, in the middle of treatment and then at the end of three months. Kidney ultrasound will be performed at the beginning and end of the study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital (clinic of nephrology)

Full name of responsible person

Maryam Hami MD

Street address

Ghaem Hospital, AhmadAbad Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi Dr.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Dr Elahe Monazah

Position
Nephrology Fellowship

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Ghaem Hospital, AhmadAbad Ave.

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Person responsible for scientific inquiries

Contact

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Position
Associated Professor Of Nephrology

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Person responsible for updating data

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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Unidentifiable data from individuals and related information will be shared with other researchers. Study protocol, data analysis program, etc, will be shared.

When the data will become available and for how long
Access to data is always available.

To whom data/document is available
All researchers are allowed to use.

Under which criteria data/document could be used
The data can be used to research and provide new solutions by citing the source.

From where data/document is obtainable
See the email of the researcher or the journal in which

the article has been published

What processes are involved for a request to access data/document

Search in the Internet by using keywords and selecting titles or requesting them by sending an email to the researcher

Comments