

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 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)

###### Phone

+98 51 1765 9556

###### Email address

hamim@mums.ac.ir

##### 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 & Fasting 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.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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**Phone**

+98 51 3801 2738

**Email**

hamim@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi Dr.

**Street address**

Vice President of Research- Ghoreshi building- Daneshgah st.

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vcresearch@mums.ac.ir

**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

**Street address**

Ghaem Hospital, AhmadAbad Ave.

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eli.mnzh@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Maryam Hami

**Position**

Associated Professor Of Nephrology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for updating data

**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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**City**

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**Postal code**

91766-99199

**Phone**

+98 51 3801 2742

**Email**

eli.mnzh@gmail.com

## 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**