

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Evaluation of the synergistic effect of coenzyme Q10 on the incidence of contrast nephropathy in patients with chronic kidney disease

#### Protocol summary

##### Study aim

Determining the synergistic effect of coenzyme Q10 on the incidence of nephropathy contrast in patients with chronic kidney disease: a randomized control trial

##### Design

Clinical trial with a control group, with parallel groups, one blind (participants), randomized on 210 patients based on the list obtained from <http://www.jerrydallal.com/random/randomize.htm>

##### Settings and conduct

chronic kidney disease people referring to Dr.Heshmat Hospital, based on the random numbers, will be divided into two control and intervention groups. In the control group, they will receive the standard treatment such that ACE, ARB, Metformin, and NSAID drugs are stopped and NAC 1200mg. Isoosmolar contrast material and COQ10 placebo supplement will be administered up to 48 hours after receiving it. In the intervention group, in addition to above cases, COQ10 will be prescribed. In both groups, at the beginning and on the third and fifth days, the baseline level of Bun-Cr-GFR and in addition the amount of urine volume will be measured on days 0 and 3.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: GFR less than -60 years of age over 18 years  
Exclusion criteria: performing emergency PCI or CAG before receiving standard treatment 24 hours before receiving contrast- presence of liver failure- presence of multiple myeloma disease and other plasma cell disorders- single kidney patients

##### Intervention groups

Control group will receive standard treatment (ACE, ARB, metformin and NSAID drugs) will be stopped, NAC 1200mg twice a day and COQ10 placebo supplement will be prescribed from 24 hours before receiving isosmolar contrast material to 48 hours after. In the intervention group, in addition to above cases, COQ10 (100 mg) will be prescribed daily from 24 hours before receiving the contrast material until 72 hours after it.

#### Main outcome variables

The incidence or non-incidence of contrast-induced nephropathy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220921056012N1**

Registration date: **2022-12-21, 1401/09/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-12-21, 1401/09/30**

Update count: **0**

##### Registration date

2022-12-21, 1401/09/30

##### Registrant information

##### Name

Parham Porteghali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 990 566 5900

##### Email address

p.porteghali@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-23, 1401/08/01

##### Expected recruitment end date

2023-06-21, 1402/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the synergistic effect of coenzyme Q10 on the incidence of contrast nephropathy in patients with chronic kidney disease

**Public title**  
Evaluation of the synergistic effect of coenzyme Q10 on contrast nephropathy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
GFR lower than 60 age upper than 18 years  
**Exclusion criteria:**  
perform urgent PCI or CAG before receiving standard care 24 hours before receiving contrast presence of liver failure presence of multiple myeloma disease and other plasma cell disorders single kidney patients

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **210**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The website <http://www.jerrydallal.com/random/randomize.htm> will be used for randomization. The randomization of this study will be by the blocked randomization method. Based on the list obtained from this website, each person will be randomly assigned to the control or intervention group using 6 random blocks with the number of 35 blocks in a ratio of 1:1. Using this method, each person is assigned one of the letters A or B to each group, and the list of codes obtained from this website will be provided to the project researchers for randomization, and each patient with chronic kidney disease with a GFR of less than 60 Those who meet the inclusion criteria will be entered the plan according to the assigned code. The steps to use this site will be as follows: we will enter the website through the <http://www.randomization.com> link. Then, by entering the number of samples and the number of considered blocks, select the option on the left and the website will automatically generate the randomization list and people will be placed in the offending groups A and B, and the output file will be usable.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
For blinding, placebos completely identical in terms of

color, smell, shape and size to the COQ10 drug will be prepared for this study. The COQ10 drug used for the patients of this project will also be placed in unlabeled cans without any label (only it is obvious to the person giving the medicine) and will be available to the patients. For this purpose, the COQ10 supplement will be placed in capsules of a large and appropriate size, and in contrast to the placebo, the same-sized capsule will be filled with a suitable filler such as lactose by a pharmaceuticals colleague present at the Faculty of Pharmacy and will be given to the control group; to be similar in appearance.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**  
Ethics committee of Guilan University of Medical Sciences

**Street address**  
in front of 17 Shahrivar Educational-Therapeutic Center, Shahid Siyadati St. Namjo St. , Rasht

**City**  
Rasht

**Province**  
Guilan

**Postal code**  
4193955588

**Approval date**  
2022-08-28, 1401/06/06

**Ethics committee reference number**  
IR.GUMS.REC.1401.286

## Health conditions studied

### 1

**Description of health condition studied**  
Contrast-induced nephropathy

**ICD-10 code**  
N 14.1

**ICD-10 code description**  
Nephropathy induced by other drugs, medicaments and biological substances

### 2

**Description of health condition studied**  
chronic kidney disease

**ICD-10 code**  
N18.9

**ICD-10 code description**

Chronic kidney disease, unspecified

## Primary outcomes

### 1

#### Description

Contrast nephropathy that occurs if Cr increases and urine volume decreases less than 0.5 cc/kg/h for at least 6 hours will be considered equivalent to acute kidney injury

#### Timepoint

In both groups, at the beginning and on the third and fifth days, the baseline level of Bun-Cr-GFR and in addition the amount of urine volume will be measured on days 0 and 3.

#### Method of measurement

Blood and urine laboratory tests to check Bun-Cr-GFR and urine volume

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: this group will receive standard and routine treatment in such a way that ACE, ARB, metformin and NSAID drugs will stopped and NAC drug 1200mg twice a day from 24 hours before receiving isosmolar contrast material to 48 hours after it, plus placebo will prescribed. Placebos will be completely identical to COQ10 in terms of color, smell, shape and size, and capsules of the same size as COQ10 will be filled with a suitable filler such as lactose and will be given to this group; to be similar in appearance.

#### Category

Placebo

### 2

#### Description

Intervention group: In this group, in addition to the items mentioned in the control group, COQ10 supplement (with a dose of 100 mg) will be prescribed daily from 24 hours before receiving the contrast medium until 72 hours after it.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dr. Heshmat hospital

##### Full name of responsible person

Parham Porteghali

#### Street address

15 Khordad Street, Rasht, Iran.

#### City

Rasht

#### Province

Guilan

#### Postal code

4193955588

#### Phone

+98 13 3366 3070

#### Email

heshmat@gums.ac.ir

#### Web page address

<https://heshmat.gums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Mohammadreza Naghipour

##### Street address

Deputy of research and technology of Guilan university of medical sciences, in front of 17 Shahrivar, Shahid Siyadati St. Namjo St. ,Rasht, Iran

##### City

Rasht

##### Province

Guilan

##### Postal code

419371311

##### Phone

+98 13 3333 5128

##### Email

oia.int@gums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Rasht 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

Rasht University of Medical Sciences

**Full name of responsible person**

Parham Porteghali

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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15 Khordad Street, Rasht, Iran.

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Parham Porteghali

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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**Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Yasaman Borghei

**Position**

nurse

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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yas.borghei74@gmail.com

**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