Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 COQ10placebo 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 COQ10placebo 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

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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 pharmaceutics 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.
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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
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Province
Guilan
Postal code
419371311
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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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Person responsible for scientific inquiries

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Person responsible for updating data

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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