Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of curcumin on the prevention of contrast induced nephropathy: A randomized double blind clinical trial

Protocol summary

Study aim
The effect of curcumin on the incidence of contrast-induced nephropathy

Design
This is a triple blinded randomized controlled clinical trial with a parallel group design of 454 patients, in which a random number table was used for randomization.

Settings and conduct
Patients include all subjects who receive IV. Contrast agent (except the candidate for renal artery angiography) and refer to Velayat, Imam Reza and Ghaem Hospitals and the physician's office. All volunteers, care providers and statistician are blinded after assignment to intervention. So that, the supplements containers were coded as A and B by a non-researcher person and remained confidential until data analysis. The placebos are similar to the supplements regarding the weight and color.

Participants/Inclusion and exclusion criteria
Hepatic failure, Biliary obstruction, End-stage renal insufficiency, acute renal insufficiency, A history of reaction to contrast media, Taking potentially nephrotoxic medicines, Pulmonary oedema, Gastrointestinal disorders, Multiple myeloma, Exposure to contrast media within 7 days before the procedure, Pregnancy, Taking N-acetyl cysteine, teofiline, dopamine, fenoldopam, manitol, and NaHCO3 within 48 h before coronary angiography.

Intervention groups
The drug group (n = 227), will receive the curcumin and the control group (n = 227), will take the placebo of the same shape, weight and color with the drug every 8 hours at a dose of 500 mg, from two days before the injection of I.V. contrast agent to 48 hours after the intervention.

Main outcome variables
Increased serum creatinine levels after 48 hours of contrast agent injection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210413050958N2**
Registration date: **2021-12-18, 1400/09/27**
Registration timing: **prospective**

Last update: **2021-12-18, 1400/09/27**
Update count: **0**

Registration date
2021-12-18, 1400/09/27

Registrant information

Name
Maryam Saberi-Karimian

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effects of curcumin on the prevention of contrast induced nephropathy: A randomized double blind clinical trial

Public title
Effect of curcumin on the prevention of contrast induced nephropathy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
All subjects who receive IV. contrast agent (except renal artery angiography candidates)
Exclusion criteria:
Hepatic failure (Child-Pugh Score B or C) Biliary obstruction End-stage renal insufficiency (eGFR less than 15 mL/min) Acute renal insufficiency (BUN/Creatinine more than 20) A history of reaction to contrast media Taking potentially nephrotoxic medicines (48 h before and 24 h after the procedure) Pulmonary oedema Gastrointestinal disorders (such as diarrhea, vomiting, dehydration, bleeding, malabsorption, indigestion, etc.) Multiple myeloma Exposure to contrast media within 7 days before the procedure Pregnancy Taking N-acetyl cysteine, teofiline, dopamine, fenoldopam, manitol, and NaHCO3 within 48 h before coronary angiography.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **227**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method will be used, so that blocks with size 4 of the combination of letters A and B (ABBA, ABAB, AABB, BAAB, BBAA, BABA) are selected to the required number using a table of random numbers and individuals are assigned to groups according to the created sequence.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The random allocation sequence is made using the table of random numbers. Sequentially numbered sealed envelopes are used to implement the random allocation sequence which opened by a person not involved in the project. The participants, care providers and statistician are blinded after assignment to intervention. So that, the powders bottles are coded by a non-researcher person and remain confidential until data analysis. Moreover, In addition, placebo powder is similar to supplement powder in shape, weight and color.
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
Research Council, Ghoreishi bildings, Daneshgah Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Approval date
2021-11-16, 1400/08/25
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.571

Health conditions studied

1

Description of health condition studied
Nephropathy induced by contrast agents
ICD-10 code
N14.1
ICD-10 code description
Nephropathy induced by other drugs, medicaments and biological substances

Primary outcomes

1

Description
Increased serum creatinine level
Timepoint
Before the intervention and 48 hours after contrast agent injection
Method of measurement
Creatinine kit

Secondary outcomes

1

Description
Blood urea nitrogen
Timepoint

Before the intervention and 48 hours after contrast agent injection

Method of measurement

Blood urea nitrogen kit

2

Description

Cell blood count

Timepoint

Before the intervention and 48 hours after contrast agent injection

Method of measurement

Sysmex Cell Counter

3

Description

Creatinin

Timepoint

Before the intervention and 48 hours after contrast agent injection

Method of measurement

Serum creatinin kit

Intervention groups

1

Description

Intervention group: In treatment group (n=227), curcumin is taken orally in subjects will be received from two days before I.V. contrast agent injection up to 48 hours after the intervention. Curcumin is provided by Sami Labs LTD company.

Category

Prevention

2

Description

Control group: In the control group (n=227), placebo of the same shape, weight and color with drug will be taken orally by subjects from two days before I.V. contrast agent injection up to 48 hours after the intervention. Placebo is provided by Sami Labs LTD company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Mohammad Hadi Saeed Modaghegh

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2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Gholamali Maamouri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Maryam Saberi-Karimian
Position
Associate professor
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Biochemistry
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Raw data will be shared upon a reasonable request from the corresponding author.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Following a reasonable request, deidentified data will be shared.
When the data will become available and for how long
After publication of paper(s) upon a reasonable request
To whom data/document is available
Study PI and executive team
Under which criteria data/document could be used
For reasonable research or clinical purpose
From where data/document is obtainable
Maryam Saberi-Karimian
What processes are involved for a request to access data/document
Direct e-mail
Comments