Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of Crocus sativus extract on prevention of nephropathy induced by coronary angiograpy : A triple blind randomized placebo controlled trial

Protocol summary

Study aim
The aim of this study will be to evaluate the effect of saffron extract capsule on prevention of contrast-induced nephropathy in patients undergoing coronary angiography.

Design
Randomised controlled clinical trial and triple blind, parallel study.Each group consists of sixty patients.

Settings and conduct
This study is conducted at Shahid Beheshti Hospital in Qom and is blinded by placebo

Participants/Inclusion and exclusion criteria
Inclusion criteria:patients undergo elective coronary angiography. Exclusion criteria:pre-existing end-stage renal disease requiring dialysis, cardiogenic shock ,serum creatinine level above 5 mg/dl

Intervention groups
Patients undergoing coronary angioplasty are divided into treatment groups with saffron extract capsules and placebo capsules that resemble medication.

Main outcome variables
Serum cratinine

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170112031893N6**
Registration date: **2020-01-06, 1398/10/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-06, 1398/10/16**
Update count: **0**

Registration date
2020-01-06, 1398/10/16

Registrant information

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Name of organization / entity
Qom University of medical science

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-12-21, 1399/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effect of Crocus sativus extract on prevention of nephropathy induced by coronary angiograpy : A triple blind randomized placebo controlled trial

Public title
Evaluation the effect of Crocus sativus extract on prevention of nephropathy induced by coronary angiograpy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
patients undergo elective coronary angiography
Exclusion criteria:
pre-existing end-stage renal disease requiring dialysis cardiogenic shock serum creatinine level above 5 mg/dl

Age
From **12 years** old to **90 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly allocated into two groups using random numbers table developed by Random Allocation Software

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, patients, statistical analyst and physicians are not aware of the allocation of drugs and placebo, and someone outside the group is aware of the allocation of treatment.The placebo is a combination of starch with edible color that is similar to the saffron capsule.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qom University of Medical Sciences

Street address
Vice chancellor for research of Qom University of Medical Sciences, Safashar road, Qom, Iran

City
Qom

Province
Ghoum

Postal code
87366-37169

Approval date
2019-11-05, 1398/08/14

Ethics committee reference number
IR.MUQ.REC.1398.100

Health conditions studied

1

Description of health condition studied
Contract induced nephropathy

ICD-10 code
N14.1

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

Primary outcomes

1

Description
serum creatinin

Timepoint
3 Day before angiograohy and 3 day after angiography

Method of measurement
blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Treatment group with saffron extract capsule (containing 1 gram) for 5 days before angiography

Category
Treatment - Drugs

2

Description
Control group: Placebo group with starch capsule (containing 1 gram) for five days before angiography

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahıd Beheshtı Hospital

Full name of responsible person
Seyyed Fakhreddin Hejazi

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Sponsors / Funding sources

1

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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
Ghoum 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

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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
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
No - There is not 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