

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation the effect of Crocus sativus extract on prevention of nephropathy induced by coronary angiography : 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

Name

Hossein Yusefi

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 angiography : A triple blind randomized placebo controlled trial

Public title

Evaluation the effect of Crocus sativus extract on prevention of nephropathy induced by coronary angiography

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

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Province

Ghous

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**

Shahid Beheshti 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

Contact

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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