Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of Crocin effect on the contrast induced nephropathy following coronary angiography or angioplasty: A randomized controlled trial

Protocol summary

Study aim
Evaluating Crocin efficacy in preventing contrast induced nephropathy

Design
This is a double blind randomized controlled trial using permuted block randomization to allocate 100 participants into two groups using the pre-designed blocks, each block consisting of a random permutation of the patient. Neither the nurse nor laboratory assistant and patients are aware of allocations. The researcher gives either Crocin or placebo for three consecutive doses to patients based on their group and will provide them with information needed, then the ward's nurse will do the standard hydration therapy 12 hrs before and after PCI and collects urine samples after each hydration therapy and BUN/Cr lab test will be ordered by the cardiologist for 72 hrs after PCI while the patient is being discharged.

Settings and conduct
This is a double blind randomized controlled trial using Permuted block randomization taking place in kermanshah city, Imam Ali heart center. Patients, nurses and laboratory assistant have been blind and only the researcher will allocate patients using permutated blocks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: coronary or peripheral angiography with or without intervention; Cr > 1.2 mg/dL and 30 <GFR < 60 mL/min; systolic pressure of greater than 90 mm Hg. Exclusion criteria: hypersensitivity to saffron; end-stage renal disease on dialysis.

Intervention groups
Participants are divided in two groups, control and intervention group. The intervention group not only will receive 3 consecutive doses of 30 mg Crocin the night before PCI and two nights after that, but also will get standard hydration therapy based on EF either with normal saline or half saline whilst in control group we will use placebo plus standard hydration therapy based on EF.

Main outcome variables
MDRD GFR; NGAL; cystatin Creatinine GFR; Mehran Risk Score; Dose to GFR ratio; contrast volume

General information

Reason for update

Acronym
CEPCIN

IRCT registration information
IRCT registration number: **IRCT20200202046335N1**
Registration date: **2020-05-13, 1399/02/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-13, 1399/02/24**
Update count: **0**

Registration date
2020-05-13, 1399/02/24

Registrant information

Name
lida shojaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3427 6489

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lida.shojaei@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-29, 1398/06/07

Expected recruitment end date
2020-05-27, 1399/03/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Crocin effect on the contrast induced nephropathy following coronary angiography or angioplasty: A randomized controlled trial

Public title

Crocin in acute kidney injury

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Undergoing coronary or peripheral angiography with or without intervention Cr > 1.2 mg/dL and 30 <GFR < 60 mL/min Systolic pressure of greater than 90 mm Hg No contraindications to hydration or contrast agent

Exclusion criteria:

History of hypersensitivity to saffron End-stage renal disease on dialysis Acute renal failure Pregnancy or lactation Emergent coronary angiography, ST elevation myocardial infarction (STEMI), or cardiogenic shock Patient receiving N-acetylcysteine or sodium bicarbonate Platelets less than or equal to 100,000/mm3 Left Ventricular ejection fraction less than 30 History of Kidney transplant

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization is a way to randomly allocate a participant to a treatment group, while maintaining a balance across treatment groups. Each “block” has a specified number of randomly ordered treatment assignment. For example, if you had treatment groups A and B, and you plan to enroll 20 new patients, your blocks might look like this: B B A B A A B A B B A A B A A B B A B A this means first patient goes to treatment group B, second patient goes to group B... Note that each block has 10 As and 10Bs, maintaining a balance of the two despite the random order.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since both groups in this clinical trial receive standard pre-treatment hydration protocol in order to prevent contrast-induced nephropathy(CIN), first participants are provided with information regarding their risk of developing CIN and the need to hydrated enough with or without Crocin. They are told that they might benefit from taking Crocin or not, but there is no side effect for sure. Then the control group takes placebo while the intervention group takes three doses of Crocin for three days. Neither participants nor nurses and laboratory assistants are aware of allocations.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

5th floor, Kakh building, Western Khorram avenue, Golrizan street

City

Kermanshah

Province

Kermanshah

Postal code

6714657495

Approval date

2020-02-03, 1398/11/14

Ethics committee reference number

IR.KUMS.REC.1398.1152

Health conditions studied

1

Description of health condition studied

Contrast induced nephropathy

ICD-10 code

N14.1

ICD-10 code description

Nephropathy induced by other drugs, medicaments and biological substances

Primary outcomes

1

Description

BUN & Creatinin

Timepoint

Before intervention and 24 and 72 hrs after that

Method of measurement

blood urine nitrogen and creatinine lab test

2

Description
(NGAL)Neutrophilic Gelatinase Associated Lipocaline
Timepoint
before and 8 hrs after angiography
Method of measurement
urine sample collection in urine sample containers

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 3 consecutive oral doses of 30 mg crocina brand tablets. before and 24 and 48 hrs after PCI. of note is that since crocina tablets are 15 mg, each time the patient is given two tablets at the same time.
Category
Prevention

2

Description
Control group: 3 consecutive oral doses of placebo before and 24 and 48 hrs after PCI.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Heart Center
Full name of responsible person
Shima Esfandyari
Street address
5th floor, Kakh building, Western Khorram avenue, Golrizan street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
vice chancellery for research and technology of kermanshah university of medical sciences, building number2, shahid beheshti Blvd
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Shima Esfandyari
Position
student
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

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

Title and more details about the data/document

The primary outcome measure after identifying

When the data will become available and for how long

After publication

To whom data/document is available

Academic institutions and people working in businesses

Under which criteria data/document could be used

as a base for other researches

From where data/document is obtainable

Dr. Shima Esfandyari's email: esfandyarishyma@gmail.com

What processes are involved for a request to access data/document

Maximum one month after delivering the email

Comments