

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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 permuted 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)

##### Phone

+98 83 3427 6489

##### Email address

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/mm<sup>3</sup> 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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##### Province

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##### Postal code

6714657495

##### Phone

+98 83 3843 8310

##### Email

esfandyarishyma@gmail.com

## 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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##### Phone

+98 83 3837 0541

##### Email

fnajafi@kums.ac.ir

#### 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 scientific inquiries

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Shima Esfandyari

**Position**

pharmacy student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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**Name of organization / entity**

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**Full name of responsible person**

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**Position**

pharmacy student

**Latest degree**

Ph.D.

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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**