

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of crocin on prevention of atrial fibrillation after coronary artery bypass grafting (CABG) or valve replacement: a triple-blind, randomized, placebo-controlled trial

#### Protocol summary

##### Study aim

prevention of atrial fibrillation after CABG or valve replacement surgery by adding crocin to drug regimen

##### Design

Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

##### Settings and conduct

80 patients that refer to Imam Reza hospital for heart surgery and complete the inclusion criteria will be included in this triple-blind, randomized, placebo-controlled trial. All of them will be monitored for 72 hrs after surgery and if they show AF rhythm for at least 5 minutes and confirmed by ICU physician, this will be considered as final outcome.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: candidates for heart surgery including CABG or valve replacement 70 yr > age > 18 yr taking ACEIs/ARBs, beta-blockers, statins and aspirin for CABG patients exclusion criteria: have pacemaker renal failure ( $45 \geq$  GFR) hepatic failure (hepatic enzymes > 3 times of upper normal limit ) sensitivity to crocin or saffron history of taking anti-inflammatory or anti-oxidant drugs via two weeks before surgery thyroid dysfunction have AF rhythm history of heart surgery pregnancy and lactation

##### Intervention groups

intervention group includes patients taking 15 mg crocin tablets two times a day from three days before to three days after surgery. control group includes patients taking placebo tablets two times a day from three days before to three days after surgery.

##### Main outcome variables

Incidence of AF; hospital stay length; High-sensitivity C-reactive protein (hs-CRP) concentration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120520009801N4**

Registration date: **2020-12-15, 1399/09/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-15, 1399/09/25**

Update count: **0**

##### Registration date

2020-12-15, 1399/09/25

##### Registrant information

##### Name

Amir Hooshang Mohammadpour

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1882 3255

##### Email address

mohamadpoorah@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-01-19, 1399/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of the effect of crocin on prevention of atrial fibrillation after coronary artery bypass grafting (CABG) or valve replacement: a triple-blind, randomized, placebo-controlled trial

### Public title

Evaluation of the effect of crocin on prevention of atrial fibrillation after heart surgery

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Candidates for heart surgery including CABG or valve replacement 70 yr > age > 18 yr Taking ACEIs/ARBs, beta-blockers, statins and aspirin for CABG patients

#### Exclusion criteria:

Have pacemaker Renal failure ( $45 \geq$  GFR) Hepatic failure (hepatic enzymes > 3 times of upper normal limit ) Sensitivity to crocin or saffron History of taking anti-inflammatory or anti-oxidant drugs via two weeks before surgery Thyroid dysfunction Have AF rhythm History of heart surgery Pregnancy and lactation

### Age

From **18 years** old to **70 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Alternate block randomization using [www.randomization.com](http://www.randomization.com). Each block has 4 members and The aforementioned site selects twenty blocks out of quadruple blocks at random so that finally 80 patients can be included in the study. The allocation concealment method is also the use of opaque sealed envelopes with random sequences obtained from the random allocation step.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

After taking the drug or placebo for three days by the patient who has been kept blind to the use of the drug or placebo, the patient is introduced to a nurse in the hospital and the medication is prescribed by the nurse (therapist). In addition, the evaluator (physician) who is different from the therapist (nurse) and does not know which drug the patient has received and is aware only of the assigned code, performs the relevant evaluations. After registration, the results are given to the person

who performs the data analysis in the form of a code, and the data analysis is performed without the knowledge of the data analyzer, and all confidential information is recorded and stored without mentioning the patient's name.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mashhad University of Medical Sciences

##### Street address

Ethic committee of Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91375-345

#### Approval date

2020-10-26, 1399/08/05

#### Ethics committee reference number

IR.MUMS.REC.1399.469

## Health conditions studied

### 1

#### Description of health condition studied

Atrial fibrillation after heart surgery

#### ICD-10 code

I48.0

#### ICD-10 code description

Paroxysmal atrial fibrillation

## Primary outcomes

### 1

#### Description

The incidence of atrial fibrillation

#### Timepoint

Through 72 hrs after heart surgery

#### Method of measurement

Holter monitoring

## Secondary outcomes

## 1

### Description

hs-CRP blood concentration

### Timepoint

Before surgery and 3 days after surgery

### Method of measurement

Laboratory

## 2

### Description

Oxidative stress

### Timepoint

Before surgery and 3 days after surgery

### Method of measurement

Laboratory - malondialdehyde assay

## 3

### Description

The incidence of ventricular and supra-ventricular arrhythmias

### Timepoint

Through 72 hrs after heart surgery

### Method of measurement

Holter monitoring

## 4

### Description

Length of hospital stay

### Timepoint

From heart surgery to discharge

### Method of measurement

Counting of hospitalizations days

## Intervention groups

## 1

### Description

Intervention group: It includes patients who receive 15 mg crocin tablets made by Sami Saz under the brand name Krocina twice a day for three days before to three days after surgery. The drug is taken by the patient himself and at home during the three days before the surgery and during the three days after the surgery by the nurses working in the intensive care unit.

### Category

Prevention

## 2

### Description

Control group: It includes patients who receive a placebo twice a day, three days before to three days after surgery, which has been prepared in the Pharmaceutics Laboratory of Mashhad School of Pharmacy. The drug is taken by the patient himself and at home during the three days before the surgery and during the three days after the surgery by the nurses working in the intensive care unit.

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Raza hospital

#### Full name of responsible person

Amirhooshang Mohamadpoor

#### Street address

Imam Raza square., Imam Raza hospital

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

91375-345

#### Phone

+98 51 3854 3031

#### Email

support@rpsi.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohsen Tafaghodi

#### Street address

Daneshgah street., Ghoreyshi bulding

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9138813944

#### Phone

+98 51 3841 1538

#### Email

vcresraech@mums.ac.ir

#### 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**

Amir Hooshang Mohammadpour

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

School of Pharmacy, Mashhad University of Medical Sciences

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mohamadpoorah@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

all collected deidentified IPD

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

only available for people working in academic institutions

**Under which criteria data/document could be used**

only available for people working in academic institutions and there is not another condition

**From where data/document is obtainable**

mohamadpoorah@mums.ac.ir

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

mohamadpoorah@mums.ac.ir

**Comments**