

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 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 ($45 \geq \text{GFR}$) 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 lenght; 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

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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 ($45 \geq \text{GFR}$) 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. 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 Pharmaceuticals 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Daneshgah street., Ghoreyshi bulding

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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

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
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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

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