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 ≥ 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)

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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 ≥ 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
Lenght 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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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
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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
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