Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Investigating the anti-inflammatory effect of colchicine in patients undergoing coronary artery bypass graft (CABG) in Semnan kosar hospital in 1401: A randomized clinical trial

Protocol summary

Study aim
Studying the anti-inflammatory effect of colchicine in patients undergoing coronary artery bypass graft in Kosar Semnan hospital

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized into two identical groups, single-center, with a sample size of 90 people.

Settings and conduct
Kosar Semnan hospital; 45 patients receive daily colchicine (1 mg daily) plus atorvastatin 80 mg daily from 3 days before surgery to 4 days after surgery. 45 patients also receive only atorvastatin 80 mg daily from 3 days before surgery to 4 days after surgery. The participant, the principal investigator, and the health care personnel who will evaluate and collect the results will not know about the grouping of the patients and the type of drugs.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The age range of people over 30 and under 80; informed consent; Need for CABG surgery. Exclusion criteria: Patients should have contraindications to colchicine or atorvastatin; Patients with a history of severe liver diseases; Patients who have creatinine clearance less than 50; Patients with a history of atrial fibrillation or atrial flutter or 2nd and 3rd-degree heart block.

Intervention groups
Intervention group: 45 patients receive daily colchicine (1 mg daily) plus atorvastatin 80 mg daily from 3 days before surgery to 4 days after surgery. Control group: 45 patients received only atorvastatin 80 mg daily from 3 days before surgery to 4 days after surgery.

Main outcome variables
CRP serum level; Interleukin 6.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220907055908N1**
Registration date: **2022-09-18, 1401/06/27**
Registration timing: **prospective**

Last update: **2022-09-18, 1401/06/27**
Update count: **0**

Registration date
2022-09-18, 1401/06/27

Registrant information
Name
Ahmad Nouri
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6527 9076
Email address
ahmadnouri@semums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-10-12, 1401/07/20
Expected recruitment end date
2024-01-10, 1402/10/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigating the anti-inflammatory effect of colchicine in patients undergoing coronary artery bypass graft (CABG) in Semnan kosar hospital in 1401: A randomized clinical trial

Public title

Investigating the anti-inflammatory effect of colchicine in patients undergoing coronary artery bypass graft

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients over 30 years old and under 80 years old patients needing CABG surgery Informed consent

Exclusion criteria:

patients should have contraindications to colchicine or atorvastatin patients with a history of severe liver diseases patients who have creatinine clearance less than 50. patients with a history of atrial fibrillation or atrial flutter or 2nd and 3rd-degree heart block patients with autoimmune diseases or a history of taking immunosuppressive drugs in the last 1 month patients with heart failure Ejection Fraction < 35% patients with a history of muscle conflicts patients of taking fibrate drugs patients with leukopenia or active infection patients with acute coronary syndrome

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Given that in this study, matching is going to be done based on gender and age group, and we want the number of participants in the intervention and control groups to be balanced as much as possible, so the randomization Stratified permuted block randomization method is used in this study. The age range of patients is 30 to 80 years. Therefore, patients are divided into two groups, 30-55 years old (younger) and 56-80 years old (older), based on the cut-off point in the middle of this range (55 years). According to the above-mentioned gender and age grouping, eligible patients are classified into 4 stratums: Younger men, older men, younger women, older women Considering that the study is of parallel type and two groups (parallel), the allocation of eligible patients (according to the defined entry and exit criteria) to the intervention and comparison groups is done separately in each of the above-mentioned strata. The two intervention and comparison groups should be matched in terms of age group and gender. The sample size in each group is 45 people (90 people in total). We use blocks of four with numbers 1 to 6 as follows (in each block, a means the intervention group and b means the comparison group): 1-aabb 2-abba 3-abab 4-baba 5-baab 6-bbaa By choosing the numbers using the table of random numbers based on the numbers one to six, select the above blocks in order and from left to right, the eligible people of each stratum in the order of entering the study and after obtaining informed consent to one of the two groups a or We attribute b. This selection is made 22 times and the first 88 eligible people are assigned to the groups. For the last two people, we use a tap or a line to complete the sample list of 90 people and complete the balance.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both groups receive atorvastatin. Therefore, this drug does not require blinding. Regarding colchicine, a placebo will be used. That is, colchicine is given to the intervention group, and a placebo (instead of colchicine and completely similar to it in terms of appearance) is given to the control group. The drugs (or placebos) are placed in coded packages and are available to the researcher in the clinic. The researcher gives each patient a package (containing medicine or placebo), and the package delivery is based on the code specified for each participant (from the first to the ninety). The patients and the researcher will not be aware of the content of the package. Only the collaborator of the project (who is responsible for concealment management and also has the randomization list) is aware of the list and codes, which at the end of the study and after the analysis (or in (in case of emergency) can reveal the code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Semnan, Basij Boulevard, Semnan University of Medical Sciences

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2022-08-29, 1401/06/07

Ethics committee reference number

IR.SEMUMS.REC.1401.152

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Interleukin 6

Timepoint

Before and after the intervention

Method of measurement

ELISA method

2

Description

CRP

Timepoint

Before and after the intervention

Method of measurement

Spectrophotometry

3

Description

LDH

Timepoint

Before and after the intervention

Method of measurement

Spectrophotometry

4

Description

ESR

Timepoint

Before and after the intervention

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

AF rhythm occurrence

Timepoint

Before and after the intervention

Method of measurement

Electrocardiogram(¬ECG)

2

Description

Gastrointestinal side effects (nausea, heartache, diarrhea and vomiting)

Timepoint

after the intervention

Method of measurement

Examination

3

Description

Death

Timepoint

after the intervention

Method of measurement

Examination

Intervention groups

1

Description

Intervention group: After conducting an interview and taking history and medical and medical records, 6 cc of blood was taken from the patient and after centrifugation and serum separation, it was kept at -70 degrees Celsius. 45 patients receive daily colchicine (1 mg daily) plus atorvastatin 80 mg daily from 3 days before surgery to 4 days after surgery. On the 8th day of the study, blood is taken from the patients again and the desired factors including CBC, serum CRP and interleukin 6 are measured by ELISA method and according to the kit's instruction.

Category

Treatment - Drugs

2

Description

Control group: 45 patients receive only atorvastatin 80 mg daily from 3 days before surgery to 4 days after surgery.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Bahador Bagheri

Street address

Semnan, Amin St

City

Semnan

Province
Semnan
Postal code
3519899951
Phone
+98 23 3345 1336
Email
kosarhos@semums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Majid Mirmohammadkhani
Street address
Semnan, Basij Boulevard, Semnan University of Medical Sciences
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3344 1022
Email
majidmirmohammadkhani@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Seyedeh Zahra Banihashemian
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Semnan, Basij Boulevard, Semnan University of Medical Sciences
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
seyedehzahra.banihashemian@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Ahmad Nouri
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Basij Boulevard, Semnan University of Medical Sciences
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
ahmadnouri@semums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Seyedeh Zahra Banihashemian
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Basij Boulevard, Semnan University of Medical Sciences
City
Semnan
Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

seyedehzahra.banihashemian@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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