Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effect of Colchicine on incidence of Major Adverse Cardiac Events (MACE) in the patients with Acute Coronary Syndrome (ACS) during the first 6 months of Colchicine use

Protocol summary

Study aim

Determination of the effect of Colchicine on Major Adverse Cardiac Events (MACE) in patients with Acute coronary Syndrome (ACS) during the first 6 months of Colchicine use

Design

Two arm parallel group randomized triple blinded clinical trial, with control group, The permutation block randomization method with four blocks will be used

Settings and conduct

A triple blinded randomized clinical trial involving 240 patients with ACS in AlZAHRA HEART HOSPITAL OF SHIRAZ who have undergone coronary angiography. Patients will be divided into two groups randomly. Group1: Standard treatment of ACS plus placebo. Group2: Standard treatment plus 0.5 mg per day Colchicine for 6 months. Subsequently we will identify patients with MACE within 6 months of admission and will compare them across both groups. Blindness: Patients (by giving a placebo), Person who follows up the patients by phone, Statistical analyzer

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have completed the informed consent form, Aged 40-70 years with history of chest pain who have undergone coronary angiography with the aim of medical treatment or who have undergone total or near total revascularization, Whose information and follow ups are completed. Exclusion criteria: Patients with history of hypersensitivity to colchicine, Moderate renal dysfunction (GFR<50), Hepatic dysfunction (ALT> 1.5 * ULN), Thrombocytopenia, Leukopenia. Pregnant patients, Lactating women, and women at risk of pregnancy. Patients who are already taking colchicine, Patients who have undergone CABG, Patients with LVEF less than 30%

Intervention groups

One group will receive a standard treatment of ACS plus placebo for 6 months, and the other group will receive standard treatment of ACS plus 0.5 mg per day colchicine for 6 months

Main outcome variables

All cause Mortality, Stroke, Decompensated HF, Hospitalization due to ACS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201117049420N1**
Registration date: **2020-11-22, 1399/09/02**
Registration timing: **retrospective**

Last update: **2020-11-22, 1399/09/02**
Update count: **0**

Registration date

2020-11-22, 1399/09/02

Registrant information

Name

Mehdi Akrami

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-03-19, 1398/12/29

Trial completion date

2020-09-20, 1399/06/30

Scientific title

Evaluation of the effect of Colchicine on incidence of Major Adverse Cardiac Events (MACE) in the patients with Acute Coronary Syndrome (ACS) during the first 6 months of Colchicine use

Public title

Evaluation of the effect of Colchicine in the patients with Acute Coroanry Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have completed the informed consent form Patients aged 40-70 years with history of chest pain who have undergone Coronary Angiography with the aim of medical treatment or who have undergone Total or Near Total Revascularization Whose information and follow ups are completed

Exclusion criteria:

1. Patients with history of hypersensitivity to Colchicine 2. Patients with history of Moderate Renal Dysfunction (GFR<50) 3. Patients with history of Hepatic Dysfunction (ALT> 1.5 * ULN) 4. Patients with history of Thrombocytopenia and or Leukopenia 5. Pregnant patient, Lactating women, and women at risk of Pregnancy 6. Patients who are already taking Colchicine 7. Patients who have undergone CABG (Coronary Artery Bypass Grafting) 8. Patients with LVEF less than 30%

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **240**

Actual sample size reached: **249**

Randomization (investigator's opinion)

Randomized

Randomization description

The permutation block randomization method with four blocks will be used. This method is one of the most widely used random methods that largely guarantees equality of groups. To do this, we first name the groups A, B and there are 4 different placements of these two letters, of course, blocks of 2, 6, etc. can also be considered. But blocks of 4 are used more often. The four permutations of the two letters A, B are AABB, ABAB, ABBA, BBAA, BABA, BAAB. Each of these is a block of size 4 that contains two experimental and two control groups, such as the AABB permutation, meaning that of the four selected individuals, the first and the second group A (group A can be a test or a control) and The second two belong to group B (group B can be a test or a control randomly by throwing a coin to determine which test A and B are to be tested and, for example, suppose that experiment A and control B are selected). We assign these 6 permutations to the numbers 1 through 6 as follows. 1. AABB 2. ABAB 3. ABBA 4. BBAA 5. BABA 6. BAAB By using the random number table, we extract numbers from the table, and depending on the number of randomly extracted numbers that are one of the numbers 0 to 9 and depending on whether one of the numbers is 1 to 6, each block We choose the number assigned to these numbers, select each of the blocks assigned to these numbers, so that 60 blocks of the four are selected. If the numbers are 0, 7, 8, and 9, we will exclude it and continue this order to provide a complete list for the whole sample size. (Randomization can also be done using a computer): 0001: study 0002: control 0003: control 0004: study 0005: study 0006: control 0007: control 0008: study 0009: control 0010: study 0011: control 0012: study 0013: study 0014: control 0015: study 0016: control 0017: study 0018: control 0019: control 0020: study 0021: study 0022: control 0023: control 0024: study 0025: control 0026: study 0027: control 0028: study 0029: study 0030: control 0031: study 0032: control 0033: study 0034: control 0035: control 0036: study 0037: study 0038: control 0039: control 0040: study 0041: control 0042: study 0043: control 0044: study 0045: study 0046: control 0047: study 0048: control 0049: study 0050: control 0051: control 0052: study 0053: study 0054: control 0055: control 0056: study 0057: control 0058: study 0059: control 0060: study 0061: study 0062: control 0063: study 0064: control 0065: study 0066: control 0067: control 0068: study 0069: study 0070: control 0071: control 0072: study 0073: control 0074: study 0075: control 0076: study 0077: study 0078: control 0079: study 0080: control 0081: study 0082: control 0083: control 0084: study 0085: study 0086: control 0087: control 0088: study 0089: control 0090: study 0091: control 0092: study 0093: study 0094: control 0095: study 0096: control 0097: study 0098: control 0099: control 0100: study 0101: control 0102: study 0103: study 0104: control 0105: control 0106: control 0107: study 0108: study 0109: control 0110: control 0111: study 0112: study 0113: study 0114: control 0115: study 0116: control 0117: control 0118: study 0119: study 0120: control 0121: control 0122: control 0123: study 0124: study 0125: control 0126: control 0127: study 0128: study 0129: study 0130: control 0131: study 0132: control 0133: control 0134: study 0135: study 0136: control 0137: control 0138: control 0139: study 0140: study 0141: control 0142: control 0143: study 0144: study 0145: study 0146: control 0147: study 0148: control 0149: control 0150: study 0151: study 0152: control 0153: control 0154: control 0155: study 0156:

study 0157: control 0158: control 0159: study 0160: study 0161: study 0162: control 0163: study 0164: control 0165: control 0166: study 0167: study 0168: control 0169: control 0170: control 0171: study 0172: study 0173: control 0174: control 0175: study 0176: study 0177: study 0178: control 0179: study 0180: control 0181: control 0182: study 0183: study 0184: control 0185: control 0186: control 0187: study 0188: study 0189: control 0190: control 0191: study 0192: study 0193: study 0194: control 0195: study 0196: control 0197: control 0198: study 0199: study 0200: control 0201: control 0202: control 0203: study 0204: study 0205: control 0206: control 0207: study 0208: study 0209: study 0210: control 0211: study 0212: control 0213: control 0214: study 0215: study 0216: control 0217: control 0218: control 0219: study 0220: study 0221: control 0222: control 0223: study 0224: study 0225: study 0226: control 0227: study 0228: control 0229: control 0230: study 0231: study 0232: control 0233: control 0234: control 0235: study 0236: study 0237: control 0238: control 0239: study 0240: study 0241: study 0242: control 0243: study 0244: control The researcher who reviews the results is not aware of the group allocation.

Blinding (investigator's opinion)
Triple blinded

Blinding description
1. Patients will blind as to whether or not they were given placebo 2. Person who follows up the patients by phone is blind as to which patients were given placebo or Colchicine 3.Statistical Analyzer is blind to patients assignment to either group

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Ethics committee of Shiraz University of Medical Sciences, Zand Blvd

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2019-09-23, 1398/07/01

Ethics committee reference number
IR.SUMS.MED.REC.1398.409

Health conditions studied

1

Description of health condition studied
Acute Coronary Syndrome

ICD-10 code
I21

ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
All Cause Mortality

Timepoint
We will follow up all patients 7 days after discharge from the hospital and then monthly to assess mortality by telephone. They will also be visited every two months

Method of measurement
Questioning the patient and the patient,s visitor; and reviewing the patient's documents

2

Description
Stroke

Timepoint
We will follow up all patients 7 days after discharge from the hospital and then monthly to assess Stroke by telephone. They will also be visited every two months

Method of measurement
Questioning the patient and the patient,s visitor; and reviewing the patient's documents

3

Description
Decompensated Heart Failure

Timepoint
We will follow up all patients 7 days after discharge from the hospital and then monthly to assess Decompensated Heart Failure by telephone. They will also be visited every two months

Method of measurement
Questioning the patient and the patient,s visitor; and reviewing the patient's documents

4

Description
Hospitalization due to typical chest pain (Acute Coronary Syndrome)

Timepoint
We will follow up all patients 7 days after discharge from the hospital and then monthly to assess Hospitalization due to typical chest pain (Acute Coronary Syndrome) by

telephone. They will also be visited every two months

Method of measurement

Questioning the patient and the patient,s visitor; and reviewing the patient's documents

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: This group will receive standard treatment of ACS plus 0.5 mg per day Colchicine for 6 months

Category

Treatment - Drugs

2

Description

Control Group: This group will receive standard treatment of ACS plus Placebo for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Heart Hospital of Shiraz

Full name of responsible person

Mehdi Akrami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Web page address

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mehdi Akrami

Position

Cardiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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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 data of study participants can be shared after unidentified individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data will be provided to researchers only to verify its accuracy
From where data/document is obtainable
Applicants can send their request via the following email: akrami.mi@gmail.com
What processes are involved for a request to access data/document
The applicant must confirm his / her identity by e-mail, and after confirming his / her identity, he / she must send a formal request from his / her institution to the address which will be sent to him / her by mail. Then, after receiving their request by mail, the requested Data will be sent within 3 months
Comments