Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effect of Colchicine therapy in patient presenting with non ST-elevation myocardial infarction

Protocol summary

Study aim
Evaluation of the effect of Colchicine therapy in patients presenting with non ST-elevation myocardial infarction

Design
Randomized, superiority, parallel group with double blind clinical trial. Simple randomization was performed using sealed envelope. Sample size calculated according to high sensitive CRP as the main outcome and error of the first kind=5% and second type=10% and Comparison of two means formula, per group 70 patients.

Settings and conduct
The study will performed in 2019-2020 in Ghaem & Imam Reza hospitals in mashhad. Patients in intervention and control groups respectively take Colchicine (0.5mg tiwce daily if weight more than 75 Kg & 0.5mg daily if weight less than 75 Kg or GFR less than 50) and placebo. For patients, evaluators and analysts will be blinded. Initial laberatory tests Include CBC diff, hsCRP, ESR, Total cholesterol, HDL & LDL cholesterol, TG, Cr, CPK, ALP, AST, ALT, hsTroponin at hospitalize time and after 4 weeks will checked. By comparing data, results of the study will achieve.

Participants/Inclusion and exclusion criteria
Condition of entrace: Patients presenting with non STEMI
Non-entry condition: Renal failure & hemodialysis, GFR<30, thrombocytopenia, Sever hepatic failure, Dyspepsia, Chronic diarrhea, Under treatment by corticosteroids or immunosuppressive medications or Diltiazem or verapamil

Intervention groups
In intervention group and control group, patients will be treated by Colchicine and placebo

Main outcome variables
high sensitive CRP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190601043780N1**
Registration date: **2019-08-26, 1398/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-26, 1398/06/04**
Update count: **0**

Registration date
2019-08-26, 1398/06/04

Registrant information

Name
Hossein Naghedinia

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3841 4936

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naghediniah951@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-10, 1398/03/20

Expected recruitment end date
2020-04-08, 1399/01/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Colchicine therapy in patient presenting with non ST-elevation myocardial infarction

Public title

Effect of Colchicine in patient presenting with non ST-elevation myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient presenting with non ST-elevation myocardial infarction

Exclusion criteria:

Patients under hemodialysis GFR<30 thrombocytopenia Severe Liver Failure (Liver enzyme > 3 times of normal) dyspepsia or chronic diarrhea Under treatment by corticosteroids or immunosuppressive medications Under treatment by verapamil or diltiazem

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by Enclosed envelope

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients initially divide in groups 1 and 2, using simple randomization method. Both groups, receive another drug wich add to main medication that is packed in the same package as No. 1 or 2. The Physician and other Partners did not know the numbers assigned to the drug or placebo. The relevant information is provided in a closed envelope by a pharmaceutical company. After the data collection and analysis are completed, the envelope will be open and drug and placebo group will be identified.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of medicine science, Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9186617415

Approval date

2018-11-20, 1397/08/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.088

Health conditions studied

1

Description of health condition studied

Non-ST elevation (NSTEMI) myocardial infarction

ICD-10 code

I21.4

ICD-10 code description

Non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

hs-CRP

Timepoint

At the beginning of the study (before the intervention) and 4 weeks after the start of taking colchicine

Method of measurement

Biochemistry Lab (human hs crp elisa kit)

Secondary outcomes

1

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

At the beginning of the study (before the intervention) and 4 weeks after the start of taking colchicine

Method of measurement

Biochemistry Lab

2

Description

mean platelet volume

Timepoint

At the beginning of the study (before the intervention) and 4 weeks after the start of taking colchicine

Method of measurement

hematology Lab

3

Description
LDL cholesterol
Timepoint
At the beginning of the study (before the intervention) and 4 weeks after the start of taking colchicine
Method of measurement
Biochemistry Lab

Intervention groups

1

Description
Intervention group: Patients more than 75 kg of body weight take 1 mg/day colchicine and patients less than 75 Kg of body weight take 0.5 mg/day of colchicine for 4 weeks
Category
Treatment - Drugs

2

Description
Control group: Patients take palcebo in this group
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Gholoobi Arash
Street address
Department of Cardiology, Imam Reza hospital, Bahar Ave.
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2

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Gholoobi Arash
Street address
Department of Cardiology, Ghaem hospital, Ahmad abad Ave.
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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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vcresearch@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
Gholoobi Arash
Position
Associate professor

Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality is the Condition of attending the study for patients.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Protocol of study design Consent form for conscious Clinical study reports Data on the primary outcome and secondary outcomes
When the data will become available and for how long
3 Months after the results are published
To whom data/document is available
Researchers working in academic center
Under which criteria data/document could be used
By Email to Scientific Responsible for the Study GholoobiA@mums.ac.ir
From where data/document is obtainable
Scientific Responsible for the Study
What processes are involved for a request to access data/document
After assurance of working of applicant in academic center
Comments