

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Curcumin in the prevention of Peri-procedural Myocardial Injury following Percutaneous Coronary Intervention (PPMI)

Protocol summary

Study aim

Evaluation of the effectiveness of Curcumin in the prevention of Peri-procedural Myocardial Injury (PPMI) in patients undergoing Percutaneous Coronary Intervention (PCI) referred to Imam Ali Research Hospital Zahedan

Design

A randomized clinical trial with placebo and treatment with Curcumin groups, 2 Blinded, including 108 patients

Settings and conduct

This study will be performed on 108 patients undergoing PCI referred to Imam Ali Research Hospital in Zahedan city. Patients in the Curcumin treatment group will receive the PCI standard pretreatment protocol (aspirin, and Clopidogrel) along with Curcumin administration (1000mg- 3 days before PCI) and in the placebo group will receive the PCI standard pretreatment protocol with placebo (with the same duration). Finally, serum levels of High-Sensitivity Troponin-I (hs-Troponin-I) and High-Sensitivity C-reactive protein (hs-CRP) will be measured in 2 time periods before PCI and 24 hours after PCI to determine the effect of Curcumin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range from 18 to 80 years, Patients with ischemic heart disease or acute coronary syndrome who referred for coronary angiography with a possible clinical indication for PCI. Exclusion criteria: Severe Hepatic dysfunction (AST or ALT more than 3 times UMN), Renal dysfunction (serum creatinine more than 2.5 mg/dL or undergoing dialysis), History of revascularization (PCI or CABG).

Intervention groups

Placebo group: patient with standard PCI pretreatment protocol with placebo for 3 days before PCI, Experimental group: patient with standard PCI pretreatment protocol with 1000mg Curcumin for 3 days before PCI

Main outcome variables

High-Sensitivity Troponin-I (hs-Troponin-I), High-Sensitivity C-reactive protein (hs-CRP), stent thrombosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231125060174N1**

Registration date: **2023-12-08, 1402/09/17**

Registration timing: **prospective**

Last update: **2023-12-08, 1402/09/17**

Update count: **0**

Registration date

2023-12-08, 1402/09/17

Registrant information

Name

Kaveh OraiiYazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 2040

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dr.k.o.yazdani@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Curcumin in the prevention of Peri-procedural Myocardial Injury following Percutaneous Coronary Intervention (PPMI)

Public title

Effect of Curcumin in the prevention of Peri-procedural Myocardial Injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ischemic heart disease and candidates for PCI or acute coronary syndrome who referred for coronary angiography with a possible clinical indication for PCI Patients with acute coronary syndrome and candidates for PCI Patients have undergone elective and non-emergency PCI Consent to participate in the present study

Exclusion criteria:

using the oral steroid drugs or NSAIDs except aspirin
Active malignancy or infection
History of Myelodysplasia
Severe Hepatic dysfunction (AST or ALT more than 3 times UMN)
Pregnancy
Renal dysfunction (serum creatinine more than 2.5 mg/dL or undergoing dialysis)
History of revascularization (PCI or CABG)

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

People have been blinded: Participant and Data analyzer
Curcumin and placebo are completely similar in shape, color and administration method

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Imam Ali Research Hospital, Persian Gulf Highway, Zahedan, Iran

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Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Approval date

2023-11-20, 1402/08/29

Ethics committee reference number

IR.ZAUMS.REC.1402.306

Health conditions studied

1

Description of health condition studied

Peri-procedural Myocardial Injury

ICD-10 code

S26.9

ICD-10 code description

Injury of heart, unspecified with or without hemopericardium

Primary outcomes

1

Description

serum levels of hs-Troponin-I

Timepoint

before PCI and 24 hours after PCI

Method of measurement

Immunoassay

2

Description

serum levels of hs-CRP

Timepoint

before PCI and 24 hours after PCI

Method of measurement

Immunoassay

Secondary outcomes

1

Description

stent thrombosis

Timepoint

30 days after PCI

Method of measurement

Observation, ECG, Echocardiography

Intervention groups

1

Description

Intervention group: Receive the standard pretreatment protocol in patients undergoing Percutaneous Coronary Intervention (aspirin, and Clopidogrel) along with 1000 mg per day Oral administration of Curcumin that prepared in Mashhad Faculty of Pharmacy, for 3 days before angiography (1000mg- 3 days before PCI)

Category

Prevention

2

Description

Control group: Receive the standard pretreatment protocol in patients undergoing Percutaneous Coronary Intervention (aspirin, and Clopidogrel) along with Oral administration of Placebo that prepared in Mashhad Faculty of Pharmacy, for 3 days before angiography

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Research Hospital

Full name of responsible person

Kaveh OrailYazdani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Kaveh OrailYazdani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Latest degree

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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

There is no further information

Study Protocol

No - There is not 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