Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Oral cyclosporine effect on myocardial damage heart

Protocol summary

Summary

Abstract To study the effect of cyclosporine oral myocardial damage during coronary artery bypass surgery in Golestan HospitalIn the period 2017, 60 patients older than 18 years and below 80 years of age who were undergoing coronary artery bypass surgery and patients without liver or kidney failure or angina And was not using of drugs such as glibenclamide and nicorandil were enrolled and non randomly divided into two groups . aterf signing informed consent 4-12hr before surgery, patients with placebo or orall cyclosporine 2.5 mg per kg is administered. Intraoperative monitoring in patients undergoing cardiac and pressure. To assess the extent of myocardial injury CKMB and troponin I in patients before surgery and at 24, 48 and 72 blood samples taken after surgery. Blood tests also included preoperative hemoglobin, the red blood cell count and white, glomerular filtration hepatic transaminase and bilirubin . All patients before surgery and in the seventh day after the surgery will be performed echocardiography.

General information

Acronym

does not have

IRCT registration information

IRCT registration number: **IRCT2017031533056N2**
Registration date: **2017-06-21, 1396/03/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-21, 1396/03/31

Registrant information

Name

Marzye Dorra

Name of organization / entity

JundiShapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences

Expected recruitment start date

2017-01-19, 1395/10/30

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Oral cyclosporine effect on myocardial damage heart

Public title

Effect of cyclosporine oral myocardial injury in patients undergoing coronary artery bypass surgery hospital in Ahvaz Golestan second half of 2017: a randomized controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: - All patients who undergoing coronary artery bypass surgery . - Patients over 18 years - willingness to participate in the study Exclusion criteria - patients over 85 years - patients with unstable angina - Patients with moderate to severe renal impairment (glomerular filtration rate less than mL / min / m2 45) - developing cirrhosis of the liver - Oral administration of drugs glibenclamide or nicorandil (due to drug

interactions).

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
does not have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahwaz JundiShapur University of Medical Sciences

Street address
Ethics committee of Ahwaz JundiShapur University of Medical Sciences

City
Ahwaz

Postal code

Approval date
2017-02-07, 1395/11/19

Ethics committee reference number
IR.AJUMS.REC.1395.784

Health conditions studied

1

Description of health condition studied
Myocardial heart

ICD-10 code
151.5

ICD-10 code description
Myocardial degeneration

Primary outcomes

1

Description
Troponin_I

Timepoint
Troponin I measurements before surgery and at 24hr, 48hr and 72hr after surgery

Method of measurement
After preparing the evaluation kit little troponin (cTnI) by Golestan hospital laboratory

Secondary outcomes

1

Description
CKMB

Timepoint
CKMB measurements before surgery and at 24hr, 48hr and 72hr after surgery

Method of measurement
CKMB measurements in the laboratory Golestan Hospital

Intervention groups

1

Description
four to twelve hours before surgery given to patients cyclosporine capsules orally at a dose of 2.5 mg per kg for a single Dose under normal conditions and maitain general anesthesia and monitoring blood pressure and ECG 2- four to twelve hours before surgery given to patients placebo orally for a single Dose under normal conditions and maitain general anesthesia and monitoring blood pressure and ECG

Category
Treatment - Drugs

2

Description
Four to twelve hours before surgery to patients given placebo orally All stages of operation under normal conditions and maintain general anesthesia and monitoring blood pressure and electrocardiogram done

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
The training center - Golestan hospital-Heart surgery

Full name of responsible person
Marzye Dorra

Street address
Cui Golestan - Golestan Hospital

City
ahwaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology Development Jundishapur University of Medical Sciences
Full name of responsible person
Doctor Behzad Sharif Makhmal zadeh
Street address
Ahwaz University Department of Research and Technology Development
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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
Vice Chancellor for Research and Technology Development Jundishapur University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty