

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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 Hospital in 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 . After signing informed consent 4-12hr before surgery, patients with placebo or oral 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)

###### Phone

+98 61 3222 8037

###### Email address

dorra.m@ajums.ac.ir

##### 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 maintain  
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 maintain 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

**City**

Ahwaz

**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

**Contact****Name of organization / entity**

Ahwaz JundiShapur University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad hassan Adel

**Position**

Professor of Cardiology

**Other areas of specialty/work****Street address**

Golestan quarter-Imam Khomeini (RA) Ahvaz -  
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## Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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## Person responsible for updating data

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Ahwaz JundiShapur University of Medical Sciences

**Full name of responsible person**

Marzye Dorra

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Student

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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*