

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jul 2026

### Preconditioning effect of Remifentanil on myocardium in patients undergoing on-pump coronary artery bypass graft surgery

#### Protocol summary

##### Summary

The purpose of this study was to evaluate the effect of remifentanil preconditioning on heart during on-pump coronary artery bypass grafting (CABG). This study is a prospective randomized clinical trial on 54 patients scheduled for elective on pump CABG surgery. The patients were randomized to receive Remifentanil or normal saline. Serial samples for measurement of cardiac troponin I (cTnI) were taken at the baseline and 2, 6, 12, and 24 hours after cross-clamp release. After operation the inotrop use in ICU, lengths of ICU and hospital stay were recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138904124297N1**

Registration date: **2010-08-23, 1389/06/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-08-23, 1389/06/01

##### Registrant information

###### Name

Mohammad Javad Esmaili

###### Name of organization / entity

Shiraz University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1233 7636

###### Email address

esmaillim@sums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2010-08-23, 1389/06/01

##### Expected recruitment end date

2010-10-22, 1389/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Preconditioning effect of Remifentanil on myocardium in patients undergoing on-pump coronary artery bypass graft surgery

##### Public title

Remifentanil preconditioning in patient undergoing CABG surgery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing CABG, age <75 years, ejection criteria >30% Exclusion criteria: Any other surgeries (valve replacement), off pump patients, - MI at 2 wks prior to the study, cardiogenic shock, cardiac arrest, intra aortic balloon pump, ejection fraction <30%, TU score<9, CHF, LBBB, AV block, uncontrolled HTN

##### Age

To **75 years** old

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

No information

## Sample size

Target sample size: 54

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences

##### Street address

Zand street, shiraz

##### City

Shiraz

##### Postal code

71345-1978

#### Approval date

2010-06-27, 1389/04/06

#### Ethics committee reference number

irct-89-5110

## Health conditions studied

### 1

#### Description of health condition studied

Other functional disturbances following cardiac surgery

#### ICD-10 code

I97.1

#### ICD-10 code description

Other functional disturbances following cardiac surgery

## Primary outcomes

### 1

#### Description

Troponin I

#### Timepoint

0, 2, 6, 12, 24 hours after induction

#### Method of measurement

laboratory

## Secondary outcomes

### 1

#### Description

Hospital stay

#### Timepoint

During admission

#### Method of measurement

in days

### 2

#### Description

Inotrop use after operation

#### Timepoint

At admission time in ICU and hospital

#### Method of measurement

Inotrop use

### 3

#### Description

ICU stay

#### Timepoint

Duration admission

#### Method of measurement

in days

## Intervention groups

### 1

#### Description

Intervention group: after monitoring with 5 leads ECG and pulse oximetry and noninvasive blood pressure iv line was inserted, then after infusion of midazolam .02mg/kg and lidocaine .5% subcutaneous arterial line was inserted with 20 gauge catheter then anesthesia induced by: midazolam , .05-.15mg/kg; fentanyl, 5-10 mcg/kg; propofol, .5-1.5mg/kg; pavalon.08-.15mg/kg; morphine .1-.5mg/kg. Then anesthesia was maintained with propofol, 50-150mg/kg. First, 1mcg/kg remifentanyl was administered then .5 mcg/kg/min was infused for 30 minutes after induction and before sternotomy.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: after monitoring with 5 leads ECG and pulse oximetry and noninvasive blood pressure iv line was inserted, then after infusion of midazolam .02mg/kg and lidocaine .5% subcutaneous arterial line was inserted with 20 gauge catheter then anesthesia induced by: midazolam , .05-.15mg/kg; fentanyl, 5-10 mcg/kg; propofol, .5-1.5mg/kg; pavalon.08-.15mg/kg; morphine .1-.5mg/kg. Then anesthesia was maintained with propofol, 50-150mg/kg. Normal saline was administered instead of remifentanyl.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Faghihi Hospital

**Full name of responsible person**

Dr Mohamad Javad Esmaili fellowship of cardiac anesthesia

**Street address**

Anesthesia ward, Faghihi Hospital

**City**

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

University Of Medical sciences

**Full name of responsible person**

Dr Mohamad Hosain Dabagh Manesh

**Street address**

ZAND street-SHIRAZ

**City**

SHIRAZE

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Shiraz University Of Medical Sciences

**Full name of responsible person**

Dr Mohamad Javad Esmaili

**Position**

Resident Fluship Of Cardiac Anesthesia

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

Anesthesia Ward, Faghihi Hospital, Zand street, Shiraz, Iran

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

DR Mohamad Taghi Moinvaziri

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Profosor associated

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## Person responsible for updating data

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**Name of organization / entity**

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**Full name of responsible person**

Dr Mohamad Javad Esmaili

**Position**

Resident Fellowship Of Cardiac Anesthesia

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

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**Web page address**

**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*