

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of clinical outcomes of methylprednisolone and dexamethasone in prime solution during cardiopulmonary pump after coronary artery bypass grafting in patients candidate for bypass surgery

Protocol summary

Study aim

Comparative study of clinical outcomes of methylprednisolone and dexamethasone in prime solution during cardiopulmonary pump after coronary artery bypass grafting

Design

A randomized, controlled, double-blind with parallel groups

Settings and conduct

In this study, which will be conducted in the heart operating room of Chamran hospital in Isfahan, 62 patients undergoing coronary artery bypass surgery will enroll. Methylprednisolone and dexamethasone will be randomly used in the prime solution during cardiopulmonary pump to evaluate the duration of mechanical ventilation, days of hospitalization, bleeding, arrhythmia and inotrope intake. Participants in this study will be unaware of the type of drug being administered and analyzer will analyze the data as a code.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients undergoing coronary artery bypass grafting surgery, Consent to participate in the study
Non-inclusion criteria: History of valve surgery, Less than 40 years old and over than 60 years old, Ejection fraction less than 40%

Intervention groups

Intervention group 1: Methylprednisolone in prime solution during cardiopulmonary pump
Intervention group 2: Dexamethasone in prime solution during cardiopulmonary pump

Main outcome variables

Duration of mechanical ventilation, days of hospitalization, bleeding, arrhythmia, Inotrope intake

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170620034666N2**

Registration date: **2019-09-24, 1398/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-24, 1398/07/02**

Update count: **0**

Registration date

2019-09-24, 1398/07/02

Registrant information

Name

Mehran Shahzamani

Name of organization / entity

Isfahan university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 31 3670 1227

Email address

m.shahzamani@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-31, 1398/05/09

Expected recruitment end date

2020-02-28, 1398/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of clinical outcomes of methylprednisolone and dexamethasone in prime solution during cardiopulmonary pump after coronary artery bypass grafting in patients candidate for bypass surgery		Name of ethics committee Ethics committee of Isfahan University of Medical Sciences	
Public title Comparison of the effect of methylprednisolone and dexamethasone in prime solution		Street address Chamran hospital, Salman Farsi Blv, Isfahan	
Purpose Treatment		City Isfahan	
Inclusion/Exclusion criteria Inclusion criteria: All patients undergoing coronary artery bypass grafting surgery Consent to participate in the study Exclusion criteria: History of valve surgery Less than 40 years old and over than 60 years old Ejection fraction less than 40%		Province Isfahan	
Age From 40 years old to 60 years old		Postal code 8174673461	
Gender Both		Approval date 2019-07-27, 1398/05/05	
Phase 3		Ethics committee reference number IR.MUI.MED.REC.1398.225	
Groups that have been masked • Participant • Data analyser		Health conditions studied 1 Description of health condition studied Coronary artery bypass graft surgery ICD-10 code T82.2 ICD-10 code description Mechanical complication of coronary artery bypass graft and biological heart valve graft	
Sample size Target sample size: 62		Primary outcomes 1 Description Bleeding Timepoint After surgery Method of measurement Observation	
Randomization (investigator's opinion) Randomized		2 Description Hospitalization days Timepoint At the time of discharge Method of measurement Based on the day	
Randomization description The random number table and block randomization method will be used using http://www.randomizer.org . In this method, eligible patients are divided into blocks of 4 patients. We create random numbers using computer. Based on the determined numerical range to enter individuals in each group, half of the patients in each block will receive methylprednisolone and half of them receive dexamethasone.		3 Description Inotrope intake Timepoint After the surgery Method of measurement Based on the recorded checklist	
Blinding (investigator's opinion) Double blinded		4 Description Duration of mechanical ventilation Timepoint	
Blinding description Participants in this study will be unaware of the type of drug being administered and analyzer will analyze the data as a code.			
Placebo Not used			
Assignment Parallel			
Other design features			
Secondary Ids empty			
Ethics committees 1 Ethics committee			

At the time of discharge
Method of measurement
Based on the hour

5

Description

Arrhythmia

Timepoint

Continuously until discharge from cardiac intensive care unit

Method of measurement

Electrocardiogram

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In dexamethasone group, 8 mg dexamethasone (Iran Hormone Company) is used in the prime solution. In the first 24 hours after surgery, the patient receives 8 mg dexamethasone every 8 hours and in the second 24 hours after surgery every 8 hours 4 mg dexamethasone and it is discontinued after the third 24 hours.

Category

Treatment - Drugs

2

Description

Intervention group 2: In methylprednisolone group, 8 mg methylprednisolone (Iran Hormone Company) is used in the prime solution. In the first 24 hours after surgery, the patient receives 8 mg methylprednisolone every 8 hours and in the second 24 hours after surgery every 8 hours 4 mg methylprednisolone and it is discontinued after the third 24 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiac surgery clinic of chamran heart center

Full name of responsible person

Mehran Shahzamani

Street address

Chamran hospital, Salman Farsi Blv, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3667 1832

Email

m.shahzamani@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Research department of Isfahan University of Medical Sciences

Street address

Hezar Jarib blvd, Isfahan

City

isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

m.shahzamani@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mehran Shahzamani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Chamran hospital, Salman Farsi Blv, Isfahan

City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3670 1227
Fax
+98 31 3670 1227
Email
m.shahzamani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehran Shahzamani
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Chamran hospital, Salman Farsi Blv, Isfahan
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3670 1227
Fax
+98 31 3670 1227
Email
m.shahzamani@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehran Shahzamani
Position
Assistant professor
Latest degree

Subspecialist
Other areas of specialty/work
General Surgery
Street address
Chamran hospital, Salman Farsi Blv, Isfahan
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3670 1227
Fax
+98 31 3670 1227
Email
m.shahzamani@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After finishing the study the data will be available

When the data will become available and for how long

After publishing the article

To whom data/document is available

Faculty members

Under which criteria data/document could be used

Contacting the scientist responsible by email causes the data to be used in order to use the data in scientific research such as meta-analysis or secondary analysis.

From where data/document is obtainable

Scientific responsible can provide the study data to academic researchers without the name of individuals

What processes are involved for a request to access data/document

Just forwarding email to scientific responsible of this trial is enough

Comments