Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 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

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Iran (Islamic Republic of)

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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

Public title
Comparison of the effect of methylprednisolone and dexamethasone in prime solution
Purpose
Treatment
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%
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Double blinded
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
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Chamran hospital, Salman Farsi Blv, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-07-27, 1398/05/05
Ethics committee reference number
IR.MUI.MED.REC.1398.225

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

Primary outcomes

1

Description
Bleeding
Timepoint
After surgery
Method of measurement
Observation

2

Description
Hospitalization days
Timepoint
At the time of discharge
Method of measurement
Based on the day

3

Description
Inotrope intake
Timepoint
After the surgery
Method of measurement
Based on the recorded checklist

4

Description
Duration of mechanical ventialtion
Timepoint

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

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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

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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

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

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Person responsible for scientific inquiries

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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 menbers
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