Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of continuous infusion of low dose Methyl Prednisolone with its single dose on reducing the inflammatory mediators and improvement of renal function in patients who undergo open heart surgery

Protocol summary

Summary

This study is a clinical trial that seeks to compare post operation Prednisolone prescription effect on post Coronary Artery Bypass Graft surgery (CABG) inflammatory phase, especially on organ damage reduction, ICU stay, inflammatory mediators level and lung oxidation index between intervention and control group. Patients will be included in the study if they aged more than 18 years and underwent CABG after obtaining a verbal and written consent. Patients with any one of the following conditions will be excluded: • Recent systemic corticosteroid intake. • Bacterial or fungal infection history within the last two weeks. • Any history of adverse reaction to steroids. • Uncontrolled diabetes mellitus. • Renal failure history. • Hepatic failure or liver enzymes elevation. The study sample size is consist of two groups, 50 patients are in each group which are selected by randomization. Intervention group will be prescribed 1mg/Kg bolus dose of prednisolone plus 2mg/Kg/d steady infusion for 24 hours. But the control group will be prescribed 15 mg/kg prednisolon as a bolous sngle dose and normal saline infusion afterthat similar valume to intervvention group as placebo. Before operation C-reactive protein (CRP) and IL-6 and serum cratinin (Cr) will be checked. Post operation assessment will be classified as below: • IL-6 and CRP 6 and 24 hours after surgery • Serum Cr 24 and 48 hours after operation • Post operation Pio2/Fio2, arrhythmia, bleeding, hemodynamic indexes such as blood pressure and central vein pressure, blood sugar, WBC changes in patients, ICU stay duration, renal failure, infection, wound and gastrointestinal complications

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010022622N2**
Registration date: **2011-03-05, 1389/12/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-03-05, 1389/12/14

Registrant information

Name
Khosro Barkhordari
Name of organization / entity
Tehran Heart Center
Country
Iran (Islamic Republic of)
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+98 21 8802 9600
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Recruitment status

Recruitment complete

Funding source

Tehran Heart Center

Expected recruitment start date

2010-11-11, 1389/08/20

Expected recruitment end date

2011-05-10, 1390/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of continuous infusion of low dose Methyl Prednisolone with its single dose on reducing the inflammatory mediators and improvement of renal function in patients who undergo open heart surgery

Public title
The prednisolone prescription effect on post CABG surgery inflammatory mediators
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:1- age over 18. 2- written informed consent. 3- patients who are candidate for open heart surgery. Exclusion criteria: 1- recent use of systemic corticosteroid. 2- history of bacterial or fungal infection in the past two weeks. 3- history of sensitivity to corticosteroids. 4- uncontrolled diabetes mellitus. 5- history of renal failure 6- liver failure or elevated liver enzymes.
Age
From **18 years** old to **90 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran Heart Center Ethic Committee
Street address
Jalal Al Ahmad & North Kargar cross
City
Tehran
Postal code
1411713138
Approval date
2011-01-03, 1389/10/13
Ethics committee reference number
433

Health conditions studied

1

Description of health condition studied
coronary artery disease
ICD-10 code
I20-I25
ICD-10 code description
Ischaemic heart diseases

Primary outcomes

1

Description
Length of stay in ICU and Intubation time
Timepoint
after transferring the patient to surgery ward
Method of measurement
questionnaire

Secondary outcomes

1

Description
Reduction of inflammatory mediators
Timepoint
before, 6 and 48 hours following operation
Method of measurement
Blood test

Intervention groups

1

Description
In control group 15mg/Kg Prednisolone bolus dose before operation and after sedation will be prescribed. After operation this group will be had steady infusion of normal saline (2mg/Kg/d)
Category
Placebo

2

Description
Intervention group will be prescribed 1mg/Kg dose of prednisolone (bolous dose) before operation and 2mg/Kg/d as infusion after that.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Heart Center
Full name of responsible person
Dr Khosrow Barkhordari
Street address
Jalal Al Ahmad & North Karegar cross
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran Heart Center
Full name of responsible person
Dr Seyed Hesameddin Abbasi
Street address
North Karegar Ave. Before Jalal-e Al Ahmad highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran Heart Center
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
Tehran Heart Center
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Anesthesiologist
Other areas of specialty/work
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Person responsible for updating data

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Fax
Email
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