Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of thiamine effect on early outcome in patients with low systolic ejection fraction after cardiac surgery

Protocol summary

Summary

In this prospective study after signing inform consent,150 patients randomly assigned to either control group(75 patients) or intervention group(75 [patients). The inclusion criterion: patients who candidates to Coronary Artery Bypass Graft (CABG) without valve surgery. Exclusion criteria: age>18 yr; accompanied other surgeries; ejection fraction>40%; history of recent alcohol use or soluble vitamins; emergency surgery; off-pump CABG and sensitivity to thiamine. In intervention group after surgery and when patients arrive ICU, will receive a bolus intravenous dose of 200 mg thiamine followed by 50 mg/hr infusion for 24 hours. The control group receive normal saline as a placebo with same characteristic of thiamine solution regarding volume and other features. Before administration the thiamine the sample of blood drives for base thiamine blood level. After 24 hour again thiamine blood level will be measured. Blood lactate will be measured at times of 0,6,12 and 24 hours. TNF α will be measured giving thiamine before and 24 hr later. Intubation time, length of stay in ICU and hospital and one month mortality rate would be the secondary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702152622N3**
Registration date: **2017-05-20, 1396/02/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-20, 1396/02/30

Registrant information

Name
Khosro Barkhordari
Name of organization / entity
Tehran Heart Center
Country
Iran (Islamic Republic of)
Phone
+98 21 8802 9600
Email address
kbarkhordari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-04-07, 1396/01/18

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of thiamine effect on early outcome in patients with low systolic ejection fraction after cardiac surgery

Public title

Evaluation of thiamine effect on heart failure

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :CABG candidates; ejection fraction>40%; age >18 years old. Exclusion criteria: emergency operation; accompanying surgery; history of recent alcohol abuse; EF>40%; recent consumption of group B vitamins and Cefteriaxone; off pump CABG;

sensitivity to group B vitamins .

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

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
Ethic Comittee of Theran Faculty of Medicine

Street address
Tehran University of Medical Sciences, Keshavarz boulevard

City
Tehran

Postal code

Approval date
2017-02-06, 1395/11/18

Ethics committee reference number
IR.TUMS.MEDICINE.ERC 1395.1656

Health conditions studied

1

Description of health condition studied
Cardiac failure

ICD-10 code
I50

ICD-10 code description
Heart failure

Primary outcomes

1

Description
Blood lactate level

Timepoint
0, 6, 18, and 24 hours after intervention

Method of measurement
Bloos sample lab test

Secondary outcomes

1

Description
intubation time

Timepoint
During hospitalization

Method of measurement
clinical assessment

2

Description
Duration of hospitalization

Timepoint
During hospitalization

Method of measurement
Clinical Assessment

3

Description
length of stay in ICU

Timepoint
During hospitalization

Method of measurement
Clinical Assessment

4

Description
One-month mortality

Timepoint
1 mo after ICU admision

Method of measurement
Clinical Assessment

Intervention groups

1

Description
The intervention group receives Thiamine as 200 mg bolus dose during 30 minutes followed by 50 mg/hr to 24 hours.

Category
Treatment - Drugs

2

Description
The control group receives normal saline as the placebo similar to Thiamine administration in intervention group.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center hospital
Full name of responsible person
Khosro Barkhordari
Street address
Tehran Heart Center hospital, North Kargar St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Miss Hajar Moamaei
Street address
Tehran University of Medical Sciences, Keshavarz blvd.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran Heart Center hospital
Full name of responsible person
Dr. Khosro Barkhordari
Position
Asssistant prof
Other areas of specialty/work
Street address
Tehran Heart Center hospital, North Kargar St.
City
Tehran
Postal code
Phone
+98 21 8802 9600
Fax
Email
kh.barkhordari@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran Heart Center hospital
Full name of responsible person
Khosro Barkhordari
Position
Assistant prof
Other areas of specialty/work
Street address
Tehran Heart Center hospital, North Kargar St.
City
Tehran
Postal code
Phone
+98 912 390 3641
Fax
Email
kh.barkhordari@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran Heart Center hospital
Full name of responsible person
Dr. Khosro Barkhordari
Position
Assiistant prof
Other areas of specialty/work
Street address
Tehran Heart Center hospital, North Kargar St.
City
Tehran
Postal code
Phone
+98 21 8802 9600
Fax
Email
kh.barkhordari@gmail.com
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