

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 informed 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 Ceftioxiame; 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.

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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

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

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Position

Assistant prof

Other areas of specialty/work

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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