

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Evaluating the effect of Pentoxifylline on Urinary Neutrophil Gelatinase-Associated Lipocalin after cardiac surgery

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

Acute renal failure (ARF) is one of the most serious complications of cardiac surgery that needs to be investigated. This is a pilot study on 30 adult patients who will undergo an isolated cardiac surgery (CABG). Excluding criteria are as follows: 1- Renal failure; 2- Hepatic failure; 3-History of gastrointestinal bleeding or Central nervous system hemorrhage; 4- Severe Arrhythmia; 5-Persistent hypotension; 6- Recent corticosteroid therapy; 7-Methylxanthine treatment; 8- Severe coagulopathies; 9-Uncontrolled diabetes mellitus; 10- Sepsis; 11-Active urinary tract infection; 12 Angiography in the past 7 days; 13-Treatment with Diltiazem or Nitroprusside; 14-Collagen vascular disease. Selected patients who meet our criteria will be randomly divided into case and control groups after taking an informed consent from them. In the case group, Pentoxifylline is given 5 mg/kg as an I.V. bolus before anesthesia followed by a 1.5 mg/kg/h infusion for 3 hours after operation. Normal saline is given to the control group as a placebo. A urine specimen is taken via catheter after anesthesia and 3 and 24 hours following operation. Urine level of Neutrophil Gelatinase-Associated Lipocalin (NGAL) will be measured using ELISA method. Serum creatinine and CRP and urine creatinine will be measured before and 3 and 24 hours after operation. Demographic information, EuroSCORE and risk factors will be collected from all patients. After data analysis, the effect of Pentoxifylline on reducing ARF will be surveyed. It is thought that Pentoxifylline could reduce the incidence of acute kidney injury following open heart surgery.

Last update:

Update count: **0**

Registration date

2010-05-25, 1389/03/04

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 Heart Center - Dr. Abasali Karimi

Expected recruitment start date

2010-01-01, 1388/10/11

Expected recruitment end date

2010-07-01, 1389/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807302622N1**

Registration date: **2010-05-25, 1389/03/04**

Scientific title

Evaluating the effect of Pentoxifylline on Urinary Neutrophil Gelatinase-Associated Lipocalin after cardiac surgery

Public title

Effect of Pentoxiphyline on preventing acute kidney injury after cardiac surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Adultpatients who underwent coronary artery bypass graft surgery with a definite indication.

Exclusion criteria: 1- Renal failure; 2- Hepatic failure; 3- History of gastrointestinal bleeding or Central nervous system hemorrhage; 4- Severe Arrhythmia; 5-Persistent hypotension; 6- Recent corticosteroid therapy; 7- Methylxanthine treatment; 8-Severe coagulopathies; 9- Uncontrolled diabetes mellitus; 10- Sepsis; 11-Active urinary tract infection; 12 Angiography in the past 7 days; 13-Treatment with Diltiazem or Nitroprusside; 14- Collagen vascular disease.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple 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

Street address

North Kargar ave

City

Tehran

Postal code

1411713138

Approval date

2009-12-28, 1388/10/07

Ethics committee reference number

382

Health conditions studied

1

Description of health condition studied

Acute Renal Failure

ICD-10 code

N17.9

ICD-10 code description

Acute Renal Failure, unsepecified

Primary outcomes

1

Description

NGAL reduction

Timepoint

3 and 24 hour following operation

Method of measurement

Blood test

Secondary outcomes

1

Description

decreasing renal failure

Timepoint

24 hours after operation

Method of measurement

Serum creatinine level every 24 hours post operation

Intervention groups

1

Description

injection of Pentoxiphyline: 5mg/kg stat bolus, 1.5 mg/kg continuous infusion for 3 hours

Category

Treatment - Drugs

2

Description

Injecting placebo: Normal saline 100 cc stat bolus + 100 cc 3-hours infusion

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Dr. Khosrow Barkhordari

Street address

North Kargar Ave. Before Jalal-e Al Ahmad highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Heart Center

Full name of responsible person

Saeed Sadeghian

Street address

North Kargar Ave.

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

Full name of responsible person

Dr. Khosro Barkhordari

Position

Anesthesiologist

Other areas of specialty/work

Street address

North Kargar Ave. Before Jalal-e Al Ahmad highway

City

Tehran

Postal code

1411713138

Phone

+98 21 8802 9600

Fax

Email

kbarkhordari@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran Heart Center

Full name of responsible person

Khosrow Barkhordari

Position

Anesthesiologist

Other areas of specialty/work

Street address

North Kargar Ave. Before Jalal-e Al Ahmad highway

City

Tehran

Postal code

1411713138

Phone

+98 21 8802 9600

Fax

Email

karkhordari@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

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