Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Preoperative oral Pentoxifylline in case of CABG with severe LV dysfunction (EF≤30%) and their complications

Protocol summary

Summary

Coronary artery disease is the first cause of death in developed and underdeveloped countries around the world. Although new drugs and advanced percutanoeus techniques are of specific importance in late stages of the disease, but CABG has its specific role in management of patients. Nowadays, patients who are reffered for surgery are in more advanced stages of disease and the quality of coronary vessels is poorer. Pentoxifilline is a known drug that makes flexibility of RBCs better in microvasculature and reduces inflammatory response to CPB. In this research, we used oral pentoxifilline for patients who are candidate for CABG alone and have poor LV function (LVEF≤30%). 178 patients were devided in two groups equally (each group = 89). The drug was taken to group 1 (case) in order of 400 mg PO TDS for 3 days before operation. The control group had only routine drugs of ward. Patients with previous MI (during last 4 weeks), previous renal failure, uncontrolled diabetes and history of anti-inflamatory drug use were excluded. Samples of blood were taken before and after operation. Multiple laboratory and clinical markers including TNF-α, IL-6, Tropnin T, need for IABP, Inotropes, transfusion, Post-op CVA, post-op RF, ventilation dependency, ICU stay and death were checked.

General information

Acronym

Pre-CABG orally Pentoxiphylline effect on EF

IRCT registration information

IRCT registration number: **IRCT201107197060N1**
Registration date: **2013-05-19, 1392/02/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-19, 1392/02/29

Registrant information

Name
Soheil Mansourian
Name of organization / entity
Tehran heart center
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran Heart Center - Department of Clinical Research

Expected recruitment start date

2011-09-08, 1390/06/17

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preoperative oral Pentoxifylline in case of CABG with severe LV dysfunction (EF≤30%) and their complications

Public title

Preoperative oral Pentoxifylline in case of CABG with severe LV dysfunction (EF≤30%) and their complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were isolated CABG using

cardiopulmonary bypass pump (CPB) adult candidates with low ejection fraction (EF ≤ 30%). Exclusion criteria: previous renal failure (RF); recent myocardial infarction (MI) (less than 4 weeks ago); uncontrolled diabetes and use of anti-inflammatory drugs.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **178**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Poursina Street

City
Tehran

Postal code
1411713138

Approval date
2011-04-09, 1390/01/20

Ethics committee reference number
2579/130/90/د

Health conditions studied

1

Description of health condition studied
Coronary Artery Disease

ICD-10 code
I25

ICD-10 code description
Chronic ischaemic heart disease

Primary outcomes

1

Description
Ejection Fraction

Timepoint
pre and early post-operation

Method of measurement
echocardiography

Secondary outcomes

1

Description
Mortality

Timepoint
Early Post-Operation

Method of measurement
Clinical

Intervention groups

1

Description
In control group: only routine drugs.

Category
Treatment - Drugs

2

Description
In intervention group: Pentoxifilline 400 mg oral tablet, TDS, 3 days beside the routine drugs.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Heart Center

Full name of responsible person
Dr Soheil Mansourian

Street address
North Kargar Street

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran Heart Center

Full name of responsible person

Somaye Kalaee
Street address
North Kargar Street
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
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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