Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Postoperative NT –proBNP level in coronary artery bypass surgery with ventricular dysfunction after perioperative GIK treatment

Protocol summary

Summary

Introduction: Multiple studies assessing the supportive value of glucose–insulin–potassium (GIK) in cardiac surgery patients with low ejection fractions have only demonstrated controversial results. On the other hand, there is strong evidence of relationship between the level of N-terminal pro-B-type natriuretic peptide (NT-proBNP) and postoperative prognosis in such patients. The purpose of the present study was to elucidate the efficacy of perioperative GIK infusion on preoperative and postoperative NT-proBNP concentrations in patients with low ejection fraction, undergoing isolated on pump coronary artery bypass surgery (CABG). Methods: In double-blinded, randomized controlled study, 60 patients with low ejection fraction who required coronary surgery with case matched preoperative medications and co morbidities were selected. Patients were randomized to a GIK (n = 36) or a control (n = 24) group. The GIK group received GIK solution (500 ml DW10% + 40U regular insulin+40 mEq KCl and 2gr MgSO4) at a rate of 50 ml/h for 10 hours preoperatively until the removal of aortic cross clamp. The control group received half saline solution as placebo with an equivalent infusion rate during the same duration. Serum NT-proBNP levels were measured in blood samples before starting the GIK, at the time of anesthesia induction and 24h after surgery. The primary outcome measure was preoperative and postoperative NT-proBNP level by using the Roche Elecsys assay.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008223438N1**
Registration date: **2010-10-05, 1389/07/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2010-10-05, 1389/07/13

Registrant information

Name
Mahnoosh Foroughi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Research Deputy, School of Medicine, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2010-09-01, 1389/06/10

Expected recruitment end date

2010-12-01, 1389/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Postoperative NT –proBNP level in coronary artery bypass surgery with ventricular dysfunction after perioperative GIK treatment

Public title

Postoperative NT –proBNP level in coronary artery bypass surgery with ventricular dysfunction after perioperative GIK treatment

Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria: elective first-time CABG with cardiopulmonary bypass (CPB), LVEF≤40%; as assessed by preoperative echocardiography) and patient consent for entering the study exclusion criteria: diabetics, patients who required concomitant valvular heart surgery, preoperative use of cardiovascular support (inotropes and/or an intraaortic balloon pump), or a serum creatinine level of >200 µmol/L were considered as exclusion criteria
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Patients undergoing elective coronary bypass with low EF

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Deputy,School of Medicine
Street address
Velenjak
City
Tehran
Postal code
Approval date
2010-01-02, 1388/10/12
Ethics committee reference number
77

Health conditions studied

1

Description of health condition studied
patients with low ejection fraction, undergoing isolated on pump coronary artery bypass surgery (CABG).
ICD-10 code
-
ICD-10 code description
-

2

Description of health condition studied
Ischaemic heart diseases
ICD-10 code
I21-122-12
ICD-10 code description
Ischaemic heart diseases

Primary outcomes

1

Description
measurement of serum NT-proBNP levels
Timepoint
before the initiation of the solutions, at the time of anesthesia induction and 24h after surgery
Method of measurement
Roche Elecsys assay

Secondary outcomes

empty

Intervention groups

1

Description
The GIK group received GIK solution (500 ml DW10% + 40U regular insulin+40 mEq KCl and 2gr MgSO4) at a rate of 50 ml/h for 10 hours preoperatively until the removal of aortic cross clamp
Category
Treatment - Drugs

2

Description
The control group received half saline solution as placebo with an equivalent infusion rate during the same duration.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Modarres Hospital
Full name of responsible person
Mahnoosh Foroughi

Street address
Research and Developement Center
City
Teran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy, School of Medicine, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ali Dabbagh
Street address
Velenjak.Shahid Beheshti University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy, School of Medicine, Shahid Beheshti 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
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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