

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

Country

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 \leq 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 μ mol/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-I22-I2

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 Development Center

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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

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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**

Research and Development Center

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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