

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effect of infusion of GIK (glucose-Insulin-potassium) solution on serum lactate and central VO2 during CABG surgeries

Protocol summary

Summary

Objectives: To investigate the effect of GIK on tissues perfusion such as cardiac ischemia during coronary artery bypass surgery. The markers such as serum lactate as an indicator are used for the assessment of myocardial perfusion CVO2 after coronary artery bypass surgery. Design of the study: randomized double blind clinical trial. Sample Size: 74 patients found eligible based on the inclusion criteria. Patients were randomly divided into two groups of intervention group and placebo group. Inclusion criteria: age 80-30 years, the first heart surgery, coronary artery bypass graft surgery, the patient informed consent for inclusion EF, less than 40%. Exclusion criteria: Pregnancy; lack of informed consent; patients undergoing dialysis; 200 mmol / L \uparrow Cr; acute coronary syndrome; 5- 350 < FBS; In the circumstances that infusion of GIK will be stopped: 5.5 mmol / L <K increased cardiac markers such as troponin and CPK Interventions: Patients in the intervention group one received infusion of GIK 40 m eq kcl plus 40 unit Reg ins plus 500 cc DW 10% after induction of anesthesia then serum lactate will be measured after induction of anesthesia and insertion of central venous catheter, CVO2 sat in 0 - 24 and 48 hours will be measured. While, in the group two patients were received infusion of normal saline after induction of anesthesia. Serum lactate was measured and after central venous catheter insertion CVO2 sat was measured at 0-24 and 48 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012019470N13**

Registration date: **2016-04-10, 1395/01/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-10, 1395/01/22

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of infusion of GIK (glucose-Insulin-potassium) solution on serum lactate and central VO2 during CABG surgeries

Public title

Evaluation of the effect of infusion of GIK (glucose-Insulin-potassium) solution on serum lactate and central VO2 during CABG surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 80-30 years, the first heart surgery, coronary artery bypass graft surgery, the patient informed consent for inclusion; EF less than 40%
Exclusion criteria: Pregnancy; lack of informed consent; patients undergoing dialysis; 200 mmol / L \uparrow Cr; acute coronary syndrome; 5- 350 < FBS; In the circumstances that infusion of GIK will be stopped: 5.5 mmol / L <K increased cardiac markers such as troponin and CPK

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **74**

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 Committee of Shiraz University Of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

CP-P-9375-7915

Health conditions studied

1

Description of health condition studied

Cardiac Surgeries

ICD-10 code

197.1

ICD-10 code description

Cardiac insufficiency Heart failure following cardiac surgery or due to presence of cardiac prosthesis

Primary outcomes

1

Description

To determine the effect of GIK on serum lactate

Timepoint

At 0-24 and 48 hour after surgery

Method of measurement

Blood sample

Secondary outcomes

1

Description

To determine the effect of GIK on increasing CVO2

Timepoint

At 0-24 and 48 hour after surgery

Method of measurement

ABG of blood sample from central vein

Intervention groups

1

Description

Intervention group: After induction of anesthesia, patents received GIK (40 m eq kcl plus 40 unit Reg ins plus 500 cc DW 10%) with continuous infusion and the rate of 1 cc / kg / h to 24 h

Category

Treatment - Drugs

2

Description

Control group:patients in the control group received infusion of normal saline after induction of anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazee Hospital

Full name of responsible person

Ensieh Shahriari

Street address

Anesthesiology Office, Namazi Hospital, Zand Street

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2

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Ensieh Shahriari

Street address

Zand Street, Faghihi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street

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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

Vice Chancellor for Research, Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Ensieh Shahriari

Position

Physician, Anesthesiology Resident

Other areas of specialty/work

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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