

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of a combination of insulin resistance reducing agents pre and post coronary artery bypass grafting surgery on post-operative blood glucose and oxidative stress regulation, Shiraz, 2012.

Protocol summary

Summary

The goal of the present study was to evaluate the effect of a combination of insulin resistance reducing agents pre and post coronary artery bypass surgery on post-operative blood glucose and oxidative stress regulation. The sample size was estimated to be 92 (23 in each group). The participants of the study will be selected from the non-diabetic patients scheduled for coronary artery bypass grafting surgery. The patients will be allocated to four groups using balanced block randomization method: group 1: receives the supplement (a 20 gram pack of the supplement daily) 7 days before surgery and placebo (a pack of starch) 30 days post surgery group 2: receives the placebo 7 days before surgery and supplement 30 days post surgery group 3: receives the supplement 7 days before and 30 days post surgery group 4: receives placebo 7 days before and 30 days post surgery one week before, before the onset of the surgery, after the surgery, 1 week after and 4 weeks after surgery, blood samples will be taken and the levels of hemoglobin A1C, glucose, insulin and malon di aldehyde will be measured. Also, body composition indices were assessed in four times: one week before the surgery, before the onset of the surgery, after the surgery, 1 week after and 4 weeks after the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312102480N3**

Registration date: **2014-01-03, 1392/10/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-03, 1392/10/13

Registrant information

Name

Mohammad Hassan Eftekhari

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of a combination of insulin resistance reducing agents pre and post coronary artery bypass grafting surgery on post-operative blood glucose and oxidative stress regulation, Shiraz, 2012.

Public title

Evaluating the effect of a new supplement on recovery after open heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: male and female patients in the range of 30 to 70 years old, undergoing coronary artery bypass grafting surgery, exclusion criteria: Diabetes mellitus, Metabolic, hematological, and immune disorders, history of renal problem and CVA, taking antioxidant supplements, emergency operations, ejection fraction < 30%

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

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**

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code**Approval date**

2013-02-24, 1391/12/06

Ethics committee reference number

91-6447

Health conditions studied**1****Description of health condition studied**

Metabolic, infectious and oxidative complications of coronary artery bypass grafting surgery

ICD-10 code

T82.6, T82

ICD-10 code description

Infection and inflammatory reaction due to cardiac valve prosthesis, Unspecified complication of cardiac and vascular prosthetic device, implant and graft

2**Description of health condition studied**

Coronary Artery Disease

ICD-10 code

I25.0, I25

ICD-10 code description

Atherosclerotic cardiovascular disease, Atherosclerotic heart disease, Chronic ischaemic heart disease, unspecified,

Primary outcomes**1****Description**

plasma glucose level

Timepoint

measured in 5 steps: 1 week before surgery, on the day of surgery before and after the operation, 1 week after surgery and 1 month after surgery

Method of measurement

spectrophotometric method

2**Description**

serum insulin level

Timepoint

measured in 5 steps: 1 week before surgery, on the day of surgery before and after the operation, 1 week after surgery and 1 month after surgery

Method of measurement

Eliza

3**Description**

hemoglobin A1C

Timepoint

measured in 5 steps: 1 week before surgery, on the day of surgery before and after the operation, 1 week after surgery and 1 month after surgery

Method of measurement

HPLC

4**Description**

body composition changes

Timepoint

measured in 4 steps: 1 week before surgery, on the day of surgery, 1 week after surgery and 1 month after surgery

Method of measurement

using Body impedance analyser, skinfold measurement with caliper, and Arm muscle circumference with tape

meter

Secondary outcomes

1

Description

lipid peroxidatin level

Timepoint

measured in 5 steps: 1 week before surgery, on the day of surgery before anf after the operation, 1 week after surgery and 1 month after surgery

Method of measurement

TBARS method

Intervention groups

1

Description

group 4: receives placebo (a pack of starch daily) 7 days before and 30 days post surgery

Category

Placebo

2

Description

group 3: receives the supplement (a 20 gram pack of the supplement daily) 7 days before and 30 days post surgery

Category

Treatment - Drugs

3

Description

group 2: receives the placebo (a pack of starch daily) 7 days before surgery and supplement (a 20 gram pack of the supplement daily) 30 days post surgery

Category

Treatment - Drugs

4

Description

group 1: receives the supplement (a 20 gram pack of the supplement daily) 7 days before surgery and placebo (a pack of starch daily) 30 days post surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Heart hospital

Full name of responsible person

Dr. Hojjatollah Rousta

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Faghihi Hospital

Full name of responsible person

Street address

Zand BLVD, Shiraz

City

Shiraz

3

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Shiraz University of Medical Sciences-Vice Chancellor for Research Affairs

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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, School of

Nutrition and Food Sciences

Full name of responsible person

Marzieh Akbarzadeh

Position

PhD Candidate of Nutrition

Other areas of specialty/work

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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