

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1725 1001

###### Email address

eftekhari@sums.ac.ir

##### 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

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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*