

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Impact of consistent measurement and management of blood glucose on clinical outcomes in patients with type 2 diabetes undergoing coronary artery bypass surgery

Protocol summary

Summary

This study aim was to evaluating and measuring impact, management and consistent control of glucose on clinical outcomes of patients with diabetes II who undergoing bypass coronary artery surgery. During a year diabetic patients whom undergoing elective coronary artery bypass surgery in Madani educational heart center in Tabriz, according our inclusion criteria that having satisfied were enrolled in this study. And then randomly were divided to one of the study or control groups. And matched together according to sex, age and NYHA class. The number of sample size based on other studies has been determined 70. Before the surgery all of the patients in both groups were inform about the benefits of this research and then if they signed the consent form will continue in the study. Patients were assured that any time they can come out of research. The intervention consisted of an insulin protocol; for the control group hospital routine insulin protocol were performed and for the case group insulin protocol were done. Inclusion criteria were; Patients who underwent elective coronary artery bypass surgery and the first time (with on pump or off pump) , who the day before surgery were be hospitalized; Patients who have type 2 diabetes diagnosed during hospitalization or admission to the hospital by blood sugar test, blood sugar after a meal and a diagnosis of type 2 diabetes after glucose tolerance ; patients who did not have other heart disease exception of coronary artery disease; patients with a creatinine level less than 2, patients who did not have kidney disease; not having another heart attack or another heart surgery at same time; no previous heart surgery; positive history of past severe disease; on-emergency surgery; non-cytotoxic drugs and radiation use. Exclusion criteria were; the operation of the on pump switch to off pump; addition of other surgery such as surgery aneurysmectomy LV; performed

endarterectomy on the involved vessels; unwillingness to continuing research, patient died during the study. The number of sample size based on other studies has been determined 70. Before the surgery all of the patients in both groups were inform about the benefits of this research and then if they signed the consent form will continue in the study. Patients were assured that any time they can come out of research. Data collection tools were questioner and new insulin revised protocol for intravenous infusion of insulin and subcutaneous injection of insulin before , during and after surgery. The aim of this study is to control patients blood glucose levels.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050311712N1**

Registration date: **2015-10-30, 1394/08/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-30, 1394/08/08

Registrant information

Name

Naiyereh Pishnamaz Ahari

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1658 9680

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Recruitment status**Recruitment complete****Funding source**

Tehran University of Medical Sciences and Shahid Madani
Cardiovascular Research Center of Tabriz

Expected recruitment start date

2013-08-22, 1392/05/31

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of consistent measurement and management of
blood glucose on clinical outcomes in patients with type
2 diabetes undergoing coronary artery bypass surgery

Public title

Integrated measuring blood glucose in diabetic patients
undergoing open heart surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were; Patients who underwent elective
coronary artery bypass surgery and the first time (with
on pump or off pump) , who the day before surgery were
be hospitalized; Patients who have type 2 diabetes
diagnosed during hospitalization or admission to the
hospital by blood sugar test, blood sugar after a meal
and a diagnosis of type 2 diabetes after glucose
tolerance ; patients who did not have other heart disease
exception of coronary artery disease; patients with a
creatinine level less than 2, patients who did not have
kidney disease; not having another heart attack or
another heart surgery at same time; no previous heart
surgery; positive history of past severe disease; on-
emergency surgery; non-cytotoxic drugs and radiation
use.Exclusion criteria were; the operation of the on pump
switch to off pump; addition of other surgery such as
surgery aneurysmectomy LV; performed endarterectomy
on the involved vessels; unwillingness to continuing
research, patient died during the study.The number of
sample size based on other studies has been determined
50. Before the surgery all of the patients in both groups
were inform about the benefits of this research and then
if they signed the consent form will continue in the study.
Patients were assured that any time they can come out
of research.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences- Enqelab
Street- Tehran

City

Tehran

Postal code

*

Approval date

2010-07-20, 1389/04/29

Ethics committee reference number

766/130/92/5

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

Diabetes Mellitus

ICD-10 code

E10,E11,E1

ICD-10 code description

Diabetes Mellitus

2**Description of health condition studied**

Other specified complications of cardiac and vascular
prosthetic devices, implants and grafts

ICD-10 code

I25.1,T82.

ICD-10 code description

T82.8 Other specified complications of cardiac and
vascular prosthetic devices, implants and grafts, I25.1
coronary (artery) disease

Primary outcomes

1

Description

Blood Glucos

Timepoint

Three time every six hour before surgery and every one hour due to surgery and after surgery in ICU and every six hour after surgery in ward till discharge

Method of measurement

The level of serum

Secondary outcomes

1

Description

Creatinin

Timepoint

One time befor surgery and three time after surgery

Method of measurement

The level of serum

2

Description

Hospitalization days

Timepoint

Until discharge from the hospital

Method of measurement

Observations and patient file

3

Description

Health costs

Timepoint

At the end of the study

Method of measurement

Health costs form

4

Description

Surgical site infection

Timepoint

Beginning of study on the first, second, third, fourth and fifth after operation

Method of measurement

According fever and purulent discharge from the surgical site

Intervention groups

1

Description

Control group: this group will be undergone insulin protocol common at hospital since entering into the unit until releasing time by regular insulin subcutaneous injection in surgery unit and intensive care unit every 6 hour and venous continuous infusion in intensive care unit and secondary variables will be studied.

Category

Treatment - Drugs

2

Description

Test group: this group will be undergone a revised new protocol of insulin since entering into the unit until releasing time by regular subcutaneous insulin injection in surgery unit and intensive care unit every 6 hour and venous continuous infusion in intensive care unit and secondary variables will be studied.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Naiyereh Pishnamaz Ahari

Street address

Shahid Madani Hospital, University Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Naiyereh Pishnamaz Ahari

Street address

Nosrat St., Tohid Sq.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Shahid Madani Cardiovascular Research Center

Full name of responsible person

Naiyereh Pishnamaz Ahari

Street address

third floor, Heart Clinic Building, in front of the Shahid Madani Hospital, University Avenue

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Madani Cardiovascular Research Center

Proportion provided by this source**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**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Rahnavard

Position

PHD

Other areas of specialty/work**Street address**

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Tehran University of Medical Sciences

Full name of responsible person

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Position

Master Degree Student

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Iran University of Medical Science

Full name of responsible person

Alireza Yaghoubi

Position

Professor of Heart Surgery

Other areas of specialty/work**Street address**

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Postal code**Phone****Fax****Email**

alireza.yaghoubi@yahoo.com

Web page address

WWW.RHC.AC.IR

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