

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of two regimens of Insulin and Insulin-Metformin in glycemic control of type 2 Diabetic patients after CABG surgery

Protocol summary

Summary

The aim of this randomized double-blind clinical trial was to compare of two regimens (Insulin and Insulin plus Metformin) on glycemic control in type 2 diabetic patients after CABG Surgery in open heart ICU of Mazandaran Heart Center. A total of 100 patients, meeting eligibility criteria, were randomly allocated into the two equal groups. Three hours after extubation, the patients in the control group received regular insulin infusion according to the center protocol, as well as two placebo tablet every 12 hours and in the in the intervention group received regular insulin infusion according to the center protocol, as well as two 500 mg metformin tablets every 12 hours. Lactate, PH, BE, blood sugar, creatinin, potassium, and insulin intake were measured every 2 hours and compared between groups

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-01-21, 1389/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008084365N5**

Registration date: **2011-01-21, 1389/11/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-21, 1389/11/01

Registrant information

Name

Afshin Gholipour Baradari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

Scientific title

Comparison of two regimens of Insulin and Insulin-Metformin in glycemic control of type 2 Diabetic patients after CABG surgery

Public title

Comparison of two regimens of Insulin and Insulin-Metformin in glycemic control of type 2 Diabetic patients after CABG surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Informed written consent, Elective CABG surgery, Type 2 diabetes, Age between 35 and 75 years, Use of the cardiopulmonary pump during surgery, Hemodynamic stability (MAP> 60, absence of dangerous dysrhythmia or heart rate between 50-11) Exclusion criteria: Liver dysfunction (SGPT and SGOT greater than 75), Renal dysfunction (serum creatinine greater than 1.5 in two consecutive tests), Heart failure (ejection fraction less than 30 percent), Serum lactate greater than 5mmo /l or increased more than 2mmol /l, Serum

PH less than 7.25 or BE less than 6 mmol /l, Arterial oxygen partial pressure less than 60 mm Hg in two consecutive ABG, Use of contrast or angiography during two days before surgery, Potassium less than 3 meq/L, Nausea and vomiting, Use of metformin metabolism Inhibitor drugs such as amiodarone and cimetidine, Use of high dose inotropes more than three hours after extubation, Prolonged intubation (more than 6 hours after surgery), Need for reoperation for any reason

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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**

Mazandaran University of Medical Sciences

Street address

Moallem Square

City

Sari

Postal code

46175866

Approval date

2011-01-05, 1389/10/15

Ethics committee reference number

89-142

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

Type 2 diabetes

ICD-10 code

E11.7

ICD-10 code description

Non-insulin dependent diabetes

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

blood sugar

Timepoint

every 2 hours

Method of measurement

mg/dl-labratory kit

Secondary outcomes**1****Description**

lactate

Timepoint

every 2 hours

Method of measurement

mg/dl-laboratory kit

2**Description**

PH

Timepoint

every 2 hours

Method of measurement

laboratory kit

3**Description**

Base Exess

Timepoint

every 2 hours

Method of measurement

mmol/l, Laboratory kit

4**Description**

Creatinine

Timepoint

every 6 hours

Method of measurement

mg/dl-laboratory kit

5**Description**

potassium

Timepoint

when infused

Method of measurement

meq-form

6

Description

insulin

Timepoint

when infused

Method of measurement

unit-form

Intervention groups

1

Description

Control group: regular insulin infusion according to the center protocol, as well as two placebo tablet every 12 hours

Category

Placebo

2

Description

Intervention group: regular insulin infusion according to the center protocol, as well as two 500 mg metformin tablets every 12 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran heart center

Full name of responsible person

Rahman Ghafari- MD-cardiac surgen- Assistant Professor

Street address

Artesh Blvd

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati MD

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

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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

Mazandaran 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

Mazandaran University Of Medical Sciences

Full name of responsible person

Amir Emami Zeidi

Position

MSc of Critical care nursing-Nurse of ICU

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University Of Medical Sciences

Full name of responsible person

Afshin Gholipour Baradari MD

Position

CCMF- Assistant Professor-Chief of ICU

Other areas of specialty/work

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Person responsible for updating data

Contact

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