

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of metformin induced lactic acidosis in Type 2 Diabetic Patients after CABG Surgery

Protocol summary

Summary

The aim of this randomized double-blind clinical trial was to evaluate metformin induced lactic acidosis in Type 2 Diabetic Patients after CABG Surgery in open heart ICU of Mazandaran Heart Center. A total of 200 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 and BS levels were measured every two hours and creatinine was measured every 6 hours and compared between groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008084365N4**

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

+98 11 3326 1245

Email address

gholipourafshin@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of metformin induced lactic acidosis in Type 2 Diabetic Patients after CABG Surgery

Public title

Evaluation of metformin induced lactic acidosis in Type 2 Diabetic Patients after CABG Surgery

Purpose

Treatment

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: **200**

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

89-126

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 mellitus

Primary outcomes

1

Description

lactate

Timepoint

every 2 hours

Method of measurement

mg/dl , Laboratory kit

Secondary outcomes

1

Description

Blood suger

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 excess

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 serum level

Timepoint

Every 6 hours

Method of measurement

laboratory test

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

Sari

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

Hadi Darvishi Khezri

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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Email

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gholipourafshin@yahoo.com

Web page address

www.mazums.ac.ir

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