

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The impact of administration of micronutrients on clinical outcomes in ICU patients following open heart surgery

Protocol summary

Summary

The aim of this study was to investigate the relationship between micronutrients and the outcomes of patients with open heart surgery. A randomized, double-blind, single center, placebo-controlled study was performed on CABG patients. A total of 200 samples were randomly divided into two subgroups of ADAMEL and normal saline. The initial outcome was a 30-day mortality

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110924975N1**

Registration date: **2017-09-26, 1396/07/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-26, 1396/07/04

Registrant information

Name

Gohar Eslami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3695

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g.eslami@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran university of medical science

Scientific title

The impact of administration of micronutrients on clinical outcomes in ICU patients following open heart surgery

Public title

The impact of administration of micronutrients on clinical outcomes in ICU patients following open heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Exclusion criteria: Patients with heart failure with discharge fraction (EF) less than 40%; The history of COPD, hyperthyroidism; Occurrence of MI after surgery; Patient's need for Pace; The need for re-surgery for any reason; Previous history of heart surgery ; Inclusion criteria: The patient's willingness to participate in the study after providing information about the study and obtaining informed consent; Candidate for Non-Emergency CABG Surgery; Use of a pulmonary pump during operation; There is no history of tachyarrhythmias treated before surgery (including AF); Having hemodynamic stability (50 MAP & heart rate between 50 - 110); Age between 20 and 75 years

Age

From **20 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

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Research Deputy of Mazandaran University of Medical Sciences Moalem Square,

City

Sari

Postal code

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

IR.MAZUMS.REC.95.2468

Health conditions studied

1

Description of health condition studied

heart surgery

ICD-10 code

I79.8

ICD-10 code description

Other disorders of arteries, arterioles and capillaries in diseases classified elsewhere

Primary outcomes

1

Description

Mortality 30 Days After Surgery

Timepoint

After Surgery to 1 Month Later

Method of measurement

File

Secondary outcomes

1

Description

Arrhythmias after surgery

Timepoint

AFTER SERGERY

Method of measurement

FILE

2

Description

Charge of Hospital

Timepoint

After Surgery

Method of measurement

File

3

Description

length of Hospital

Timepoint

After Surgery

Method of measurement

FILE

4

Description

Length of Mechanical Ventilation

Timepoint

After Surgery

Method of measurement

File

5

Description

Incidence of Renal Failure

Timepoint

After Surgery

Method of measurement

File

6

Description

Length of ICU

Timepoint

After Surgery

Method of measurement

File

7

Description

Charge of ICU

Timepoint

After Surgery

Method of measurement

Intervention groups**1****Description**

Adamel, 10 CC Infusion, daily

Category

Treatment - Drugs

2**Description**

Normal Saline, 10 CC. Infusion, Daily

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**Fatemeh Zahra hospital of Mazandaran University of
Medical Sciences**Full name of responsible person**

Areia Soleimani

Street address

Sari

City

Sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Vice Chancellor for Research, Moalem 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****Person responsible for general inquiries****Contact****Name of organization / entity**

Asistance of professor of clinical pharmacy

Full name of responsible person

Gohar Eslami

PositionFaculty of Pharmacy, Mazandaran University of
Medical Sciences**Other areas of specialty/work****Street address**Faculty of Pharmacy, Payambar Azam Complex, 18
Km Farah Abad Blvd, Khazar Square**City**

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Postal code**Phone**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

Position

Asistance of Professor

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**Faculty of Pharmacy, Mazandaran University of
Medical Sciences**Full name of responsible person**

Gohar Eslami

Position

Asistance of Professor Clinical Pharmacy

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

Sari
City
Sari
Postal code
Phone
00
Fax
Email
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