Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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

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Gohar Eslami
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Mazandaran University of Medical Scienses
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Recruitment status

Recruitment complete

Funding source

Mazandaran university of medical science

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

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 و 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 MazandaranUniversity of Medical Sciencesm 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 Sergery

Timepoint

After Sergery 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 Sergery

Method of measurement

File

3

Description

lenght of Hospital

Timepoint

After Sergery

Method of measurement

FILE

4

Description

Lenght of Mechanical Ventilation

Timepoint

After Sergery

Method of measurement

File

5

Description

Incidence of Renal Failure

Timepoint

After Sergery

Method of measurement

File

6

Description

Lenght of ICU

Timepoint

After Sergery

Method of measurement

File

7

Description

Charge of ICU

Timepoint

After Sergery

Method of measurement

File

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
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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
Asistance of professor of clinical pharmacy
Full name of responsible person
Gohar Eslami
Position
Faculty of Pharmacy, Mazandaran University of Medical Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Faculty of Pharmacy, Mazandaran University of Medical Sciences
Full name of responsible person
Gohar Eslami
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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