

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Effects of intravenous lipid emulsion on improve cardiac function after open heart surgery

#### Protocol summary

##### Summary

Purpose: Clinical trial effect of intravenous lipid emulsion on improve cardiac function after open heart surgery. A total of 60 patients who underwent open heart surgery and in the ICU were hospitalized to be chosen and a double blind (Researchers and patients were unaware of the drugs) randomized using a random number table is divided into two groups. The patient in group 1 was injected normal saline (500cc) and in group 2 was injected intravenous lipid (500cc) (construction company Frezenius) emulsion 20%. During the 3-hour infusion of both solutions at 1cc /kg /h, then (EF) Ejection Fraction was measured. Inclusion criteria: Candidate for CABG surgery; consent to participate in research; The first surgery of CABG; Ef above 35 ; BMI less than 30 ; lack of familial metabolic disorder; no need for mechanical ventilation and inotrope Exclusion criteria: re-heart surgery; need to balloon pump; rate disorder during surgery and then. Primary outcome: improved heart function using echo devices before surgery and after surgery were evaluated. Secondary outcome: stay in the intensive care unit of admission in ICU after surgery until discharge or transfer to the criteria.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092412094N5**

Registration date: **2017-01-31, 1395/11/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-01-31, 1395/11/12

##### Registrant information

##### Name

Majid Razavi

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 915 110 8630

##### Email address

razavim@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2014-12-11, 1393/09/20

##### Expected recruitment end date

2015-05-11, 1394/02/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of intravenous lipid emulsion on improve cardiac function after open heart surgery

##### Public title

Clinical trial effect of intravenous lipid emulsion on improve cardiac function after open heart surgery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Candidate for CABG surgery; consent to participate in research; The first surgery of CABG; EF above 35 ; BMI less than 30 ; lack of familial metabolic disorder; no need for mechanical ventilation and inotrope

Exclusion criteria: re-heart surgery; need to balloon pump; rate disorder during surgery and then

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: 60

#### **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 Mashhad University of Medical Sciences

##### **Street address**

Ghoreishi apartment, Daneshgah street, Mashhad

##### **City**

Mashhad

##### **Postal code**

##### **Approval date**

2014-11-22, 1393/09/01

##### **Ethics committee reference number**

IR.MUMS.REC.1393.193

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

cardiac disease

#### **ICD-10 code**

I25.1

#### **ICD-10 code description**

Atherosclerotic heart disease

## **Primary outcomes**

### **1**

#### **Description**

Ejection Fraction

#### **Timepoint**

Before and after surgery

#### **Method of measurement**

Echocardiography device

## **Secondary outcomes**

### **1**

#### **Description**

Stay in intensive care units

#### **Timepoint**

Since admission to the ICU after surgery until discharge or transfer to the

#### **Method of measurement**

Observation

## **Intervention groups**

### **1**

#### **Description**

Intervention group: injected 500cc intravenous lipid (construction company Frezenius) emulsion 20% injected during the 3 hours at 1cc/kg/h.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: Patients received 500 cc normal saline during the 3-hours at 1cc /kg /h

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza Hospital

##### **Full name of responsible person**

Dr Majid Razavi

##### **Street address**

##### **City**

Mashhad

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Vice Chancellor for Research, Mashhad University of Medical Sciences

##### **Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Ghoreishi apartment, Daneshgah street, Mashhad

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research, Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Majid Razavi

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Department of Anesthesia, Imam Reza Hospital, Ibne Sina Street, Mashhad

**City**

Mashhad

**Postal code**

**Phone**

+98 51 3852 5209

**Fax**

**Email**

Razavim@mums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Majid Razavi

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Department of Anesthesia, Imam Reza Hospital, Ibne Sina

**City**

Mashhad

**Postal code**

**Phone**

+98 51 3852 5209

**Fax**

**Email**

Razavim@mums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Saeed Daghestani

**Position**

Resident of Anesthesiology

**Other areas of specialty/work**

**Street address**

**City**

Mashhad

**Postal code**

**Phone**

+98 51 3802 2711

**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*