

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of magnesium sulfate on coagulation parameters of the ROTEM system during adult liver transplant anesthesia

Protocol summary

Summary

The present study will be a randomized clinical trial that designed to evaluate effect of magnesium therapy on coagulation profiles on system, we also measured serum magnesium to confirm the effect of magnesium therapy on rotational thromboelastometry (ROTEM) parameters. Before induction of anesthesia 4ml of whole blood will be obtained through veinopuncture from each patient for ROTEM analysis. The remaining blood samples will be sent to the laboratory to measure the serum magnesium concentration. After that, each patient in group A, will receive 50 ml syringe with A label that will be infused intravenously in 5 minutes and each patient in group B, will received 50 ml syringe with B label that was infused intravenously in 5 minutes. Then, again before surgical incision 4ml of whole blood was obtained through veinopuncture from each patient for ROTEM analysis measurement of serum magnesium.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012911662N9**

Registration date: **2016-01-30, 1394/11/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-30, 1394/11/10

Registrant information

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Mohammad Ali Sahmeddini

Name of organization / entity

Shiraz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of magnesium sulfate on coagulation parameters of the ROTEM system during adult liver transplant anesthesia

Public title

Survey the effect of magnesium on coagulopathy of liver transplant patients.

Purpose

Treatment

Inclusion/Exclusion criteria

The eligible participants were all patients with end stage liver disease aged between 18 and 60 years old, who were candidates for orthotopic liver transplantation under general anesthesia. Exclusion criteria were: having a history of hepatorenal syndrome types I and II; baseline serum potassium >6 meq/l; ejection fraction <60% and cirrhotic cardiomyopathy and patients with INR <1.5.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

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**

Shiraz Medical School Research Ethic Committee

Street address

Shiraz Medical School, Zand Blvd.

City

Shiraz

Postal code

197871345

Approval date

2015-08-05, 1394/05/14

Ethics committee reference number

IR.sums.med.rec.1394.88

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

Liver transplantation

ICD-10 code

Y83.0

ICD-10 code description

Surgical operation with transplant of whole organ

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

Measurement of the coagulation profiles on rotational thromboelastometry (ROTEM) system.

Timepoint

First time, before magnesium sulfate infusion and induction of anesthesia and second time, after magnesium sulfate infusion just before surgical incision.

Method of measurement

By rotational thromboelastometry (ROTEM) system.

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

Measurement of the serum magnesium level.

Timepoint

First time, before magnesium sulfate infusion and induction of anesthesia and second time, after magnesium sulfate infusion just before surgical incision.

Method of measurement

In the lab by special kit.

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

Each patient in the intervention group , will received 1.5 gram magnesium sulfate that will be diluted with normal saline up to 50 ml with 50 ml syringe with B label that will be infused intravenously in 5 minutes.

Category

Treatment - Drugs

2**Description**

Each patient in the control group, will receive 50 ml normal saline in 50 ml syringe with A label that will be infused intravenously in 5 minutes.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Namazi Hospital Organ Transplantation Center

Full name of responsible person

Mohammad Ali Sahmeddini

Street address

Namazi Hospital, Namazi Sq

City

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

Vice-Chancellery of Research and Technology

Full name of responsible person
Dr. Seyed Basir Hashemi

Street address
Shiraz University Of Medical Sciences

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Shiraz

Grant name

Grant code / Reference number

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

Title of funding source
Vice-Chancellery of Research and Technology

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

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Associate Professor of Anesthesiology

Other areas of specialty/work

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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