

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### A clinical trial of using of "Intravenous magnesium sulphate" on deliberate hypotension and bleeding through orthognathic surgery

#### Protocol summary

##### Summary

(1) Objectives: A Randomized, double-blind, placebo-controlled assessment of the effects of intravenous magnesium sulfate during orthognathic surgery under general anesthesia on the amount of bleeding. Magnesium sulfate is a good agent for deliberate hypotension due to the interference of magnesium activation of membrane Ca-ATPase and NA-ATPase involved in ion exchange membrane during depolarization and repolarization, and thus as a cell membrane stabilizer and acts intra- cytoplasmic organelles . Magnesium sulfate acts as a vasodilator with increases prostacyclin synthesis and inhibition of enzyme activity of angiotensin converting enzyme. Although the effects of magnesium sulfate on the cardiovascular system is weak, but is dose dependent. Magnesium also reduces the stress response via conflict of NMDA receptors in the central nervous system (CNS) and reduce the release of catecholamines and sympathetic stimulation. (2) Design: A total of 60 adult patients aged 16 to 40 years will be randomly admitted to the chamran hospital requiring bimaxillary orthognathic surgery had studied. The following parameters such as: Individual patient information , medical history, the patient's hemodynamic values before- during and after surgery, duration of operation, the amount of blood loss during operation and blood products transfusion will be recorded. (3) Setting and conduct: The patients were randomly divided to receive either magnesium sulfate (group I) or saline (group II) is allocated, while anesthesiologist, nurses and patients are unaware of the content of injection (Medications prepared by other nurses and are randomly coded) . (4) Participants including major eligibility criteria: Patients with no history of systemic disease and without taking any analgesic medications criteria that were willing to cooperate in this study were enrolled; and Exclusion criteria included known allergy to the study drugs; hepatic and renal dysfunction ; patients with heart block or myocardial

damage; morbid obesity (BMI  $\geq$  35); neuromuscular disease; history of neuropathy; asthma; use of calcium channel blockers and Patients who did not sign the informed consent. (5) Intervention: Patients in the first group will be received an intravenous "Magnesium Sulfate" 30 mg / kg body weight bolus for 15 min followed by 10 mg / kg / hr dissolved in saline via pump infusion and the second group will receive " placebo" as same bolus volume of "normal salin" in a 15-minute intravenous infusion and is continued until the en of operation. (6) main outcome measures : During surgery the patient's heart rate, blood pressure and blood oxygen saturation is recorded at specified intervals and at the end of the operation the amount of blood loss and blood transfusion were recorded. And then any post-operative complications will be asked in the questionnaire .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201311051674N9**

Registration date: **2013-12-09, 1392/09/18**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-12-09, 1392/09/18

##### Registrant information

##### Name

Hamid Reza Eftekharian

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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**Recruitment status**  
**Recruitment complete**

**Funding source**  
Supported by Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

**Expected recruitment start date**  
2013-12-22, 1392/10/01

**Expected recruitment end date**  
2014-12-21, 1393/09/30

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
A clinical trial of using of "Intravenous magnesium sulphate" on deliberate hypotension and bleeding through orthognathic surgery

**Public title**  
The efficacy of "Intravenous magnesium sulfate" on bleeding through orthognathic surgery

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
Patients with no history of systemic disease and without taking any analgesic medications criteria that were willing to cooperate in this study were enrolled; and Exclusion criteria included known allergy to the study drugs; hepatic and renal dysfunction ; patients with heart block or myocardial damage; morbid obesity (BMI ≥ 35); neuromuscular disease; history of neuropathy; asthma; use of calcium channel blockers and Patients who did not sign the informed consent.

**Age**  
From **16 years** old to **40 years** old

**Gender**  
Both

**Phase**  
2

**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 Shiraz University Of Medical Sciences

##### Street address

Zand Avenue, Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Shiraz

##### City

Shiraz

##### Postal code

197871345

#### Approval date

2013-12-01, 1392/09/10

#### Ethics committee reference number

CT-P-92-6454

## Health conditions studied

### 1

#### Description of health condition studied

Bimaxillary Orthognathic Surgery

#### ICD-10 code

00

#### ICD-10 code description

00

## Primary outcomes

### 1

#### Description

Bleeding during surgery

#### Timepoint

During operation and postoperative

#### Method of measurement

CC

## Secondary outcomes

### 1

#### Description

Use of blood products

#### Timepoint

Postoperative

#### Method of measurement

CC

### 2

#### Description

Side effects of magnesium sulfate

**Timepoint**

Intraoperative

**Method of measurement**

Hemodynamic changes

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

Patients in the first group will be received "Magnesium Sulfate" an initial dose of 30 mg / kg body weight intravenously during 15 minutes and then continuously magnesium sulfate 10 mg / kg / hr via pump infusion until the end of operation.

**Category**

Treatment - Drugs

**2****Description**

The placebo group ( Normal saline) will be given an initial dose of the same volume of normal saline intravenously and infusion of normal saline continued until end of surgery.

**Category**

Treatment - Drugs

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

Shiraz Chamran Hospital

**Full name of responsible person**

Hamid Reza Eftekharian

**Street address**

Shiraz Chamran Hospital, Shiraz University Of Medical Sciences, Chamran Blvd., Shiraz

**City**

Shiraz

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

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

**Full name of responsible person**

Gholam Reza Hatam

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Zand Avenue, Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Shiraz

**City**

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**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, Shiraz 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**

Shiraz University Of Medical

**Full name of responsible person**

Hamid Reza Eftekharian

**Position**

Assistant Professor

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

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University Of Medical Sciences, Shiraz

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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*