

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### A Clinical Trial of Intravenous Infusion of "Magnesium Sulfate" During Orthognathic Surgery on Postoperative Pain.

#### Protocol summary

##### Summary

(1) Objectives: Magnesium is a physiological calcium channel blocker and a non-competitive antagonist of NMDA receptors, that theoretically could be involved in a part of the process of molecular sensitization by blocking NMDA receptors in regulation of postoperative pain. This study has tried it with magnesium sulfate intravenously during bimaxillary orthognathic surgery to review its impact on the intensity of pain after surgery and its effect on postoperative analgesic drugs consumption. Therefore We can offer prescription intraoperative magnesium sulfate intravenously during orthognathic surgery can to avoid the indiscriminate use of opioids for pain after surgery. (2) Design: A total of 50 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 opioid or analgesics 3 days before the study; use of calcium channel blockers; did not sign the informed consent will be excluded. (5) Intervention: Patients in the first group will be received an intravenous "Magnesium Sulfate" 50

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 will take analgesics were recorded. After surgery the patients were monitored for up to 4 hours in the recovery room and pain intensity (VAS) is measured by a person who was unaware of group members every half hour. In the surgical ward for 12 hours, if the drug is administered by a nurse for pain relief will be recorded. And then any post-operative complications will be asked in the questionnaire .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201307101674N7**

Registration date: **2013-07-29, 1392/05/07**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-07-29, 1392/05/07

##### Registrant information

##### Name

Hamid Reza Eftekharian

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3636 4001

##### Email address

**Recruitment status**

Recruitment complete

**Funding source**

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

**Expected recruitment start date**

2013-07-23, 1392/05/01

**Expected recruitment end date**

2014-07-21, 1393/04/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A Clinical Trial of Intravenous Infusion of "Magnesium Sulfate" During Orthognathic Surgery on Postoperative Pain.

**Public title**

Analgesic effect of intravenous "magnesium sulfate" during bimaxillary orthognathic surgery

**Purpose**

Treatment

**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  $\geq$  35); neuromuscular disease; history of neuropathy; asthma; Use of opioid or analgesics 3 days before the study; 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**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **50**

**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**

2013-07-20, 1392/04/29

**Ethics committee reference number**

CT-P-92-6010

**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**

The intensity of the pain

**Timepoint**

Every half hour for twelve hours after operation

**Method of measurement**

Visual analog scale

**2**

**Description**

Heart rate and blood pressure

**Timepoint**

Before, during and after surgery

**Method of measurement**

ECG and blood pressure monitoring device

**3**

**Description**

Duration of surgery

**Timepoint**

End of surgery

**Method of measurement**

The Minutes

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

The use of sedative or narcotic

**Timepoint**

In the recovery room and surgical ward

**Method of measurement**

Visual analog scale

**2****Description**

Magnesium Sulfate side effects

**Timepoint**

Postoperative and in the ward Surgery

**Method of measurement**

Questionnaire

**3****Description**

Urine volume

**Timepoint**

From beginning to end the operation

**Method of measurement**

cc/kg/min

**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**

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

Dr. GHolamreza Hatam

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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 Sciences

**Full name of responsible person**

Ali Asghar Hosseini

**Position**

BS

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## Person responsible for scientific inquiries

### Contact

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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*