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 ≥ 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

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Name of organization / entity

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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
2013-07-23, 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 orthognatic 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 ≥ 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 nomal 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
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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
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Zand Avenue, Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Shiraz
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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
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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