Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A clinical trial of using of "Intravenous magnesium sulphate" on delibrate 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 ≥ 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

+98 71 3636 4001

Email address
eftekharhr@sums.ac.ir

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 delibrate 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 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
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
Street address
Zand Avenue, Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Shiraz
City
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, 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
Chamran Blvd., Shiraz Chamran Hospital, Shiraz University Of Medical Sciences, Shiraz
City
Shiraz
Postal code
7183856793
Phone
+98 71 1648 3783
Fax
Email
eftekharhr@sums.ac.ir
Web page address
www.sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University Of Medical Sciences
Full name of responsible person
Hamid Reza Eftekharian
Position
Assistant Professor
Other areas of specialty/work
Street address
Chamran Blvd., Shiraz Chamran Hospital, Shiraz University Of Medical Sciences, Shiraz
City
Shiraz
Postal code
7183856793
Phone
+98 71 1648 3783

Fax
+98 71 1623 4507
Email
eftekharhr@sums.ac.ir
Web page address
www.sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University Of Medical Sciences
Full name of responsible person
Hamid Reza Eftekharian
Position
Assistant Professor
Other areas of specialty/work
Street address
Chamran Blvd., Shiraz Chamran Hospital, Shiraz University Of Medical Sciences, Shiraz
City
Shiraz
Postal code
7183856793
Phone
+98 71 1648 3783
Fax
Email
eftekharhr@sums.ac.ir
Web page address
www.sums.ac.ir

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