Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison the effect of magnesium sulfate with pregabalin on prevention of remifentanil – induced hyperalgesia in patients undergoing rhinoplasty. A randomized clinical trial

Protocol summary

Study aim

Deliberate hypotension is one of the methods used to reduce hemorrhage and improve surgical field quality, particularly in head and neck surgeries. Remifentanil is among the drugs use to reach this goal. However, one of the complications of this drug is post-operative hyperalgesia, for which an enormous number of drugs has been thoroughly have been studied. In the present study, 105 patients who undergoing rhinoplasty will be categorized into three equal groups to compare the effects of magnesium sulfate and pregabalin in reducing hyperalgesia induced by remifentanil.

Design

In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 105 patients who candidate for rhinoplasty will be enrolled in the study. Eligible patients will be categorized into three equal A, B and C groups by simple randomization table.

Settings and conduct

This is a randomized, double blinded clinical trial , single center.For blindness, all of the drugs solution(Magnesium sulfate and normal saline) of this study will be prepared in 50 ml syringes that are equal in shape and pregabalin like placebo capsule will be made by only person who aware of study's groups .Anesthesiologist, patients, all person who will collaborated in the study will not aware of patients groups.

Participants/Inclusion and exclusion criteria

A total of 105 patients in the ASA class 1 who candidate for rhinoplasty will be enrolled in the study. Exclusion criteria include history of the heart disease, pulmonary disease, liver disease, kidney disease, neurological and psychological diseases, history of the allergy to drugs such as pregabalin, magnesium sulfate, remifentanil, history of alcohol and narcotics abuse, patients who suffering from chronic pain, those who used any pain killer drugs 72 hours prior to anesthesia.

Intervention groups

Patients in the group A will receive 300 mg pregabalin one hour before entering operation room while the other two groups will be received placebo capsule.Patients in the group B will receive 30 mg magnesium sulfate at induction of anesthesia and then during anesthesia will receive infusion 10 mg/kg/hr of the magnesium sulfate, whereas patients in the groups A and C will receive 50 cc saline solution as a infusion in the same time period during anesthesia .

Main outcome variables

Postoperative Pain severity according to NRS (numerical rating scale) will be recorded and will be compared.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121204011662N12**
Registration date: **2018-02-27, 1396/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-27, 1396/12/08**
Update count: **0**

Registration date

2018-02-27, 1396/12/08

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

Expected recruitment start date
2018-02-20, 1396/12/01
Expected recruitment end date
2018-09-22, 1397/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of magnesium sulfate with pregabalin on prevention of remifentanil – induced hyperalgesia in patients undergoing rhinoplasty. A randomized clinical trial

Public title
Comparison the effect of magnesium sulfate with pregabalin on prevention of the pain severity induced by remifentanil.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A total of 105 patients in the ASA class 1 who candidate for rhinoplasty will be enrolled in the study.
Exclusion criteria:
Exclusion criteria : History of the heart diseases , pulmonary diseases, liver diseases, kidney diseases, neurological and psychological disease, history of the allergy to drugs such as pregabalin, magnesium sulfate, remifentanil, history of alcohol and narcotics abuse, patients who suffering from chronic pain, those who used pain killer drugs 72 hours prior to anesthesia.
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
All eligible patients will be randomized according to simple randomization table into three equal groups A, B, C.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blindness, All of the drugs solution(Magnesium Sulfate and normal saline) of this study will be prepared in 50 ml syringes that are equal in shape and placebo of the pregabalin in the pregabalin like capsule, by only person who aware of study's groups. Anesthesiologist, patients and all persons who will collaborated in this study, will not aware of patients groups.
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
3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.
City
Shiraz
Province
Fars
Postal code
197871345
Approval date
2018-01-15, 1396/10/25
Ethics committee reference number
Ir.sums.med.rec.1396.122

Health conditions studied

1

Description of health condition studied
Postoperative pain management following rhinoplasty.
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Severity of postoperative pain
Timepoint
In the first 6 hours postoperation, every hour and then 24 hours after operation.
Method of measurement
Numerical Rating Scale

Secondary outcomes

1

Description
Sedation Score
Timepoint
In the first 6 hours postoperation, every hour and then 24 hours after operation.
Method of measurement
Ramsey Scale

2

Description
Incidence of nausea and vomiting
Timepoint
In the first 6 hours postoperation, every hour and then 24 hours after operation.
Method of measurement
0: No nausea and vomiting, 1: Nuasea without Vomiting, 2: Both Nausea and Vomiting.

Intervention groups

1

Description
Intervention group: Patients in group A will receive 300 mg pregabalin one hour before entering operation room.
Category
Treatment - Drugs

2

Description
Intervention group: Patients in group B will receive 30 mg magnesium sulfate at induction of anesthesia and then infusion 10 mg/kg/hr during anesthesia.
Category
Treatment - Drugs

3

Description
Control group: Patients in group C will receive 10 ml saline solution at induction of anesthesia then 1ml/Kg/hr normal saline solution during anesthesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khalili training and medical center
Full name of responsible person
Mohamma Ali Sahmeddini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Seyed Basir Hashemi
Street address
Shiraz University Of Medical Sciences building, Zand Blvd.
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Fax
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Email
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Web page address
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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
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad Ali Sahmeddini

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Latest degree
Subspecialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available