

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of magnesium sulfate with pregabalin on prevention of remifentanyl - 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. Remifentanyl 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 remifentanyl.

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, remifentanyl, 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

Name

Mohammad Ali Sahmeddini

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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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 remifentanyl – 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 remifentanyl.

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, remifentanyl, history of alcohol and narcotics abuse, patients who suffering from chronic pain, those who used pain killer drugs 72 hours prior to anesthesia.

AgeFrom **20 years** old to **40 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample sizeTarget 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

lr.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: Nausea 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

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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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Full name of responsible person

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Person responsible for updating data

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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