

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Clinical trial of evaluating effect of remifentanyl in post-operative hyperalgesia and prophylactic effect of magnesium sulfate

Protocol summary

Summary

This study is going to evaluate post-operative hyperalgesia due to infusion of high dose of remifentanyl (for inducing hypotension) during rhinoplasty and prophylactic effect of magnesium sulfate on this side effect of remifentanyl. This is a double blind clinical trial on 105 candidates for Rhinoplasty in Alzahra Medical Center. Inclusion criteria are: 15 to 65 years old and no contraindication for magnesium sulfate, remifentanyl or nitroglycerin. Patients select by simple sampling and after inducing of anesthesia allocate in 3 groups (35 patients in each group). In first group 30 mg/kg magnesium sulfate inject in 10 minutes then continuous infusion of 0.05 to 0.2 µg/kg remifentanyl begin. In second group normal saline (placebo) in a similar syringe inject in 10 minutes then continuous infusion of 0.05 to 0.2 µg/kg remifentanyl begin. In third group normal saline (placebo) in a similar syringe inject in 10 minutes then continuous infusion of 1 to 20 µg/kg nitroglycerin begin. Remifentanyl and nitroglycerin inject by infusion pump and speed of infusion adjust to keep blood pressure 30% lower than base (preoperative blood pressure). For double blinding all drugs prepare and take randomization code by a coworker other than main researchers. Vital signs and total amount of drugs record in three groups. Pain measurement takes before discharge from recovery, 6 and 24 hours after surgery by Visual Analog Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071216415N3**

Registration date: **2014-08-02, 1393/05/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-02, 1393/05/11

Registrant information

Name

Mohammad Golparvar

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3220 1750

Email address

golparvar@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-10-07, 1393/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of evaluating effect of remifentanyl in post-operative hyperalgesia and prophylactic effect of magnesium sulfate

Public title

Evaluating effect of remifentanyl in post-operative hyperalgesia and prophylactic effect of magnesium sulfate on it

Purpose

Prevention

Inclusion/Exclusion criteria

Age 15 to 65 years old; ASA 1 and 2; without history of usage of neuro-psychological drugs; without history of usage of NSAIDs; no contraindication for TNG; no contraindication for magnesium sulfate; no contraindication for remifentanyl

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **105**

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 vice research of medical school of Isfahan University of Medical Sciences

Street address

Vice research of medical school; Isfahan University of Medical Sciences; Hezarjarib boulevard; Isfahan; Iran

City

Isfahan

Postal code

Approval date

2014-02-19, 1392/11/30

Ethics committee reference number

16259

Health conditions studied

1

Description of health condition studied

Hypotension due to drugs

ICD-10 code

I95.2; T65

ICD-10 code description

Hypotension due to drugs; Nitroglycerin and other nitric

acids and esters

Primary outcomes

1

Description

Severity of pain

Timepoint

Before discharge from recovery; 6 hours after surgery; 24 hours after surgery

Method of measurement

By VAS

Secondary outcomes

empty

Intervention groups

1

Description

Prescription of magnesium sulfate 30 mg/kg and continuous infusion of remifentanyl 0.05 to 0.2 microgram/kg/min

Category

Treatment - Drugs

2

Description

Prescription of placebo (normal saline) and continuous infusion of remifentanyl 0.05 to 0.2 microgram/kg/min

Category

Treatment - Drugs

3

Description

Prescription of placebo (normal saline) and continuous infusion of nitroglycerin 1 to 20 microgram/kg/min

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Medical Center

Full name of responsible person

Golparvar M. MD

Street address

Department of anesthesia, Alzahra Medical Center, Sofeh boulevard, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and technology of Isfahan
University of Medical Sciences

Full name of responsible person

Dr Alimohammad Sabzeghabaei

Street address

Research manager office, Isfahan University of
Medical Sciences, Hezarjarib Boulevard, Isfahan, Iran

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of Research and technology of Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

Golparvar M MD

Position

Associate professor in Medical School of Isfahan
University of Medical Sciences

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inquiries

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Web page address

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

