Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Efficacy of Magnesium sulfate and Tramadol as an adjunct to the Intravenous Regional Block for Controlling Postoperative Pain Following Upper Extremity Surgeries.

Protocol summary

Summary

The purpose of this study is to compare the effects of tramadol and magnesium sulfate in postoperative pain control after these surgeries. In this double-blind clinical trial of 69 patients ASA 1&2, which will be candidate for surgery of the hand and forearm,were randomly allocated into three groups of 23 patients. All patients will receive 3mg/kg lidocaine 0.5%, then for control group normal saline, group 1 magnesium sulfate and group 2 tramadol is will be injected. Demographic data will be recorded and postoperative pain which will be measured by visual analogue scale in the recovery room and ward every hour for 6 hours and then every 4 hours for 24 hours postoperatively will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040511662N6**
Registration date: **2014-05-23, 1393/03/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-05-23, 1393/03/02

Registrant information

Name

Mohammad Ali Sahmeddini

Name of organization / entity

Shiraz University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences .

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of Magnesium sulfate and Tramadol as an adjunct to the Intravenous Regional Block for Controlling Postoperative Pain Following Upper Extremity Surgeries.

Public title

Comparison of the analgesic effect of magnesium and Tramadol after local anesthesia of upper extremity.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 69 patients 15-65 years old with ASA 1&2candidates for elective hand and forearm surgery or due to trauma. Exclusion criteria: History of drug abuse; History of allergies to drugs such as local anesthetics or opioid; History of: liver diseases; cardiovascular disease; renal failure; sickle cell anemia; Raynaud's disease; coagulopathy; G6PD deficiency; seizures.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **69**

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

Shiraz University Medical Research Ethic Committee

Street address

Shiraz University of Medical Sciences ,Zand Blv

City

Shiraz

Postal code

197871345

Approval date

2014-03-09, 1392/12/18

Ethics committee reference number

CT-P-92-6256

Health conditions studied

1

Description of health condition studied

Acute Postoperative Pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Postoperative pain intensity

Timepoint

Every hour for 6 hours and then every 4 hours for 24 hours after surgery

Method of measurement

Visual Anlouge Scale

Secondary outcomes

1

Description

Nausea and Vomiting

Timepoint

Every one hour during first postoperative 24 hr

Method of measurement

Nausea is defined as urge to vomiting without ejection ofof the contents of the stomach through the mouth, Vomiting is defined asto eject of the contents of the stomach through the mouth, usually in a series of involuntary spasmic movements.

Intervention groups

1

Description

Control group: 10 cc saline in the 10 ml syringe will be injected into the patient by a resident of anesthesia who will not aware of the content of 10 cc syringe

Category

Treatment - Drugs

2

Description

Interventional group 1: 1.5 gram magnesium sulfate diluted with saline to a volume of 10 cc will be injected into the patient by a resident of anesthesia who will not aware of the content of 10 cc syringe .

Category

Treatment - Drugs

3

Description

Interventional group 2 : 100 miligram tramadol diluted with saline to a volume of 10 cc will be injected into the patient by a resident of anesthesia who will not aware of the content of 10 cc syringe .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Training and Medical Center operation room

Full name of responsible person

Mohammad Ali Sahmeddini

Street address

Chamran Training and Medical Center,Chamran Blv

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Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellery of Research and Technology
Full name of responsible person
Dr. Seyed Basir Hashemi
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Shiraz University Of Medical Sciences building,Zand Blv
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
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

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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