

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of postoperative analgesic effect of Magnesium sulfate and Gabapentin in patients undergoing laparoscopic cholecystectomy in Musavi hospital of Zanjan in 2019

Protocol summary

Study aim

Determine the postoperative analgesic effect of Magnesium sulfate and Gabapentin in patients undergoing laparoscopic cholecystectomy in Musavi hospital of Zanjan in 2019

Design

Simple randomized, controlled clinical trial of Gabapentin and Magnesium sulfate

Settings and conduct

The trial will be performed after confirming of the code of ethics and registration in IRCT at Ayatollah Mousavi Hospital in Zanjan in patients undergoing laparoscopic cholecystectomy. In pre-operative visit will provide training on how to express pain and how to work with visual analogue scale. Random cases will be divided into 3 groups of 30 people. The control group will not receive any interventions. In gabapentin group, 600mg of gabapentin will be given an hour before surgery. In the magnesium sulfate group, 50mg/kg magnesium will be infused within 100ml of normal saline during one hour per-operation. After operation using the VAS visual scale every 15 minutes till 1 hour and every 6 hours till 24 hours for checking pain. At each stage, in the case of a larger vas than 4, they will be given 25mg pethidine. After data collection, amount of drug use and VAS index will be compared statistically between the 3 groups.

Participants/Inclusion and exclusion criteria

Age 18-65/ ASA class 1,2/ BMI less than 30/ No allergy to medication/ lack of history of cardiac arrhythmia and hepatic and renal dysfunction / normal creatinine/no pregnancy or breastfeeding/no use of analgesics/no use of analgesics/absence of neuromuscular diseases

Intervention groups

There will be no intervention in Control group, in Gabapentin group they will be given 600mg gabapentin one hour before surgery, in Magnesium sulfate group they will be infused 50mg/kg Magnesium sulfate in

100ml normal saline one hour per-surgery

Main outcome variables

Pain by VAS; Time of first need of analgesics; Overall consume of analgesics

General information

Reason for update

Acronym

VAS (Visual Analogue Scale)

IRCT registration information

IRCT registration number: **IRCT20160818029414N6**

Registration date: **2019-10-21, 1398/07/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-21, 1398/07/29**

Update count: **0**

Registration date

2019-10-21, 1398/07/29

Registrant information

Name

Vahideh Rashtchi

Name of organization / entity

Zanjan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 341 1683

Email address

rashtchi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-21, 1398/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Comparison of postoperative analgesic effect of Magnesium sulfate and Gabapentin in patients undergoing laparoscopic cholecystectomy in Musavi hospital of Zanjan in 2019
Public title
Effect of Magnesium sulfate and Gabapentin in laparoscopic cholecystectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-65 years ASA I-II BMI less than 30 Normal creatinine
Exclusion criteria:
Allergy to medication History of cardiac arrhythmia and hepatic renal impairment pregnancy or breastfeeding use of analgesics use of NSAIDs Existence of neuromuscular disease
Age
From **18 years** old to **65 years** old
Gender
Both
Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with use of sample volume formula and comparison of a qualitative trait in groups
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences
Street address
Floor 5, No. 106, 25th Ave., Saadatabad
City
Tehran
Province
Tehran
Postal code
1998869153
Approval date
2019-07-09, 1398/04/18
Ethics committee reference number
IR.ZUMS.REC.1398.178

Health conditions studied

1

Description of health condition studied

Laparoscopic Cholecystectomy

ICD-10 code

K81.1

ICD-10 code description

Chronic cholecystitis

Primary outcomes

1

Description

Post operative pain

Timepoint

After surgery every 15minutes till 1hour and then every 6hours till 24hours

Method of measurement

Visual analogue scales

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Gabapentin group: one hour before surgery patient will be taken 600mg gabapentin(2 300mg capsule)

Category

Treatment - Drugs

2

Description

Intervention group: Magnesium sulfate group: 50mg/kg magnesium sulfate in 100ml normal saline will be infused to patients in one hour during surgery.

Category

Treatment - Drugs

3

Description

Control group: No medication will be taken .

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Musavi hospital

Full name of responsible person

Dr Vahideh Rashtchi

Street address

Musavi hospital, Gavazang road, Zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

Street address

Azadi Blvd., Zanjan

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Bitra Barghi

Position

Anesthetist

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Dr Vahideh Rashtchi

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Assistant Professor

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Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

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Position

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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

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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