Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Study the Effect of Intravenous of Dexamethasone versus Magnesium Sulphate on postoperative pain after laparoscopic Cholecystectomy surgery

Protocol summary

Study aim
The effect of intravenous dexamethasone and magnesium sulfate injection on pain after laparoscopic head cystectomy surgery

Design
A double-blind, randomized, phase 3 clinical trial on 60 patients with ASA class I, II, using a simple random assignment method with placement, and after the end of the study, all information was analyzed using the statistical software SPSS for Windows (Version 25, (IBM, corp were investigated.

Settings and conduct
After referring the patients to the teaching hospitals affiliated to Ahvaz Jundishapur University of Medical Sciences (Golestan and Imam Khomeini), they will be selected and randomly assigned to two groups and after obtaining permission from the Ethics Committee of Ahvaz University of Medical Sciences and completing an informed consent form. Participation in the study, patients will be included in the study based on the criteria.

Participants/Inclusion and exclusion criteria
The study inclusion criteria include patients between 18-70 years old, candidates for elective laparoscopic cholecystectomy surgery, satisfaction with the study exclusion criteria including known allergy to one of the study drugs (dexamethasone/magnesium sulfate), liver-kidney-heart dysfunction, History of taking steroid drugs before surgery, neuromuscular disease, taking opioids or painkillers within 3 days before the study, taking calcium channel blockers, not signing a written consent form.

Intervention groups
15 minutes before the start of general anesthesia, patients in group M were given a bolus dose of 50 mg/kg magnesium sulfate for 15 minutes and an infusion of 10 mg/kg magnesium sulfate in normal saline until the end of the procedure, and group D, 1 mg/kg intravenous dexamethasone 15 minutes before induction and 0.4 mg/kg/h will be given as an infusion during the procedure.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230717058811N1**
Registration date: **2023-10-16, 1402/07/24**
Registration timing: **retrospective**

Last update: **2023-10-16, 1402/07/24**
Update count: **0**

Registration date
2023-10-16, 1402/07/24

Registrant information

Name
tirazhe hazrati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 912 890 7911

Email address
hazrati.t@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-20, 1402/03/30

Expected recruitment end date
2023-07-21, 1402/04/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study the Effect of Intravenous of Dexamethasone versus Magnesium Sulphate on postoperative pain after laparoscopic Cholecystectomy surgery

Public title
Investigation and effect of intravenous injection of dexamethasone and magnesium sulfate on pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients between 18-70 years old Candidate for elective laparoscopic cere cystectomy surgery Action satisfaction
Exclusion criteria:
known allergy to one of the study drugs (dexamethasone/magnesium sulfate) Liver-kidney-heart dysfunction History of taking steroid drugs before surgery Neuromuscular disease Opioid or analgesic use within 3 days before the study Taking calcium channel blockers Failure to sign written consent
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the samples will be divided into two similar groups of 30 people using a table of random numbers, and in the pre-surgery visit, the necessary examinations will be performed, then 15 minutes before the start of anesthesia, 6 cc/kg of Ringer's normal saline will be administered to the patients. will be given and full monitoring including NIBP/ECG/pulse oximetry will be done, demographic information (age, gender, weight) and vital signs will be recorded in the questionnaire.
Blinding (investigator's opinion)
Double blinded
Blinding description
60 patients with inclusion criteria will be used in the simple random allocation method with placement. In this way, 60 numbers will be poured into a container, and for each patient, after obtaining informed consent, an envelope will be drawn from the container, and based on the odd or even numbers, they will be divided into two groups: dexamethasone and magnesium sulfate. will be allocated. The even numbers will form the dexamethasone group and the odd numbers will form the magnesium sulfate group, then in order to blind the study, the patient and the researcher and the person who will complete the questionnaires will not know the type of injectable drug and the group under investigation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Golestan Hospital Research
Street address
Golestan Ave, Golestan Hospital
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2023-06-20, 1402/03/30
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1402.057

Health conditions studied

1

Description of health condition studied
Pain after head cystectomy surgery
ICD-10 code
K91.86
ICD-10 code description
Retained cholelithiasis following cholecystectomy

Primary outcomes

1

Description
Visual Analogue Scale (VAS)
Timepoint
Based on the VAS criteria at certain times (immediately after induction, one hour, two hours and 24 hours after the operation)
Method of measurement
After the surgery, the patient will be monitored for 2 hours in recovery and the pain intensity of the patients will be measured and recorded every half hour by a

person who is not aware of the groups.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in group M will be given a bolus dose of 50 mg/kg magnesium sulfate in 15 minutes and an infusion of 10 mg/kg magnesium sulfate in normal saline until the end of the operation.
Category
Treatment - Surgery

2

Description
Intervention group: Group D will be given 1 mg/kg intravenous dexamethasone 15 minutes before induction and 0.4 mg/kg/h as an infusion during the procedure.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Tirazheh Hazrati Yadkoori
Street address
24 metery street, east sahely highway, ahvaz
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2

Recruitment center
Name of recruitment center
Golestan Hospital ahvaz
Full name of responsible person
Tirazheh Hazrati Yadkoori
Street address
Golestan Hospital Medical Education Center., Golestan Street., Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerkish
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University of medical science, Golestan street, Golestan town، Ahvaz
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Tirazheh Hazrati Yadkoori
Position
Assistant Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology

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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
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