

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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.,
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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

Street address

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 scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Tirazheh Hazrati Yadkooari

Position

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Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

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Tirazheh Hazrati Yadkooari

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