Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparative study of the effect of local infiltration of two doses of Hydrocortisone on pain and nausea and vomiting after laparoscopic cholecystectomy

Protocol summary

Study aim

General purpose : Determining and comparing the effect of local infiltration of two doses of pre-emptive hydrocortisone on pain, nausea and vomiting(PONV) After laparoscopic cholecystectomy(LC) Specific purpose : 1) Determining and comparing the mean vas score of pain intensity after surgery 2) Determining and comparing the mean vas score of intensity of PONV 3) Determining and comparing the frequency of vomiting after surgery 4) Determining and comparing the average pethidine consumption of after surgery 5) Determine and compare the average of the first time needed for analgesia 6) Determining and comparing the average of the first time needed for anti-nausea 7) Determining and comparing the frequency percentage of the number of anti-nausea doses received

Design

Clinical trial with control group, three-blind, phase 3 on 105 patients. randomized by random allocation using statistical software.

Settings and conduct

This three-blind clinical trial study will be performed on patients of Alzahra and Ayatollah Kashani Hospital in Isfahan who undergo LC due to chronic cholecystitis.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1) Age group 85-20 y 2) LC due to chronic cholecystitis 3) ASA physical status one and two Criteria for non-inclusion : 1) allergy to local anesthetics and drugs, morbid obesity, advanced respiratory diseases, kidney, blood, liver, cardiovascular 2) Chronic use of drug , beta adrenergic receptor antagonists and drug addicts 3) Pregnant women 4) mental retardation

Intervention groups

Group A: receive 100 mg of pre-emptive hydrocortisone at the surgical site. Group B: Receive 50 mg of pre-emptive hydrocortisone at the surgical site. Group C: receive cc20 preoperative normal saline at the surgical site

Main outcome variables

Reduce surgical complications، patient and medical center costs; Increase patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101211005362N26**
Registration date: **2021-07-07, 1400/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-07, 1400/04/16**
Update count: **0**

Registration date

2021-07-07, 1400/04/16

Registrant information

Name

Mohammadreza Safavi

Name of organization / entity

Anesthesiology and Critical Care Research Center, Isfahan University of Medical Sciences, Isfahan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of local infiltration of two doses of Hydrocortisone on pain and nausea and vomiting after laparoscopic cholecystectomy

Public title

Effect of local Hydrocortisone on pain and nausea and vomiting after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age group 85-20 years Case of laparoscopic cholecystectomy due to chronic cholecystitis ASA physical status one and two

Exclusion criteria:

Patients with allergies to local anesthetics and drugs, morbid obesity, advanced respiratory diseases, kidney, blood, liver, cardiovascular Chronic drug use, beta or alcohol adrenergic receptor antagonists, and drug addicts pregnant women Mental retardation

Age

From **20 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization in this study is a simple random method using random allocation software, which is an individual randomization unit and random sequencing is done using this software and based on the arrangement presented by patients. Drugs and placebo in syringes together The shape and volume of the preparation are coded depending on the content (1,2,3) and according to the sequence determined by the software, patients receive the desired material. For allocation concealment, the sequentially numbered ,sealed ,opaque envelopes or SNOSE method is used.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this three-blind study of patients and researchers and statistical analysts, the results of the study group and the drug used are not known. Medications are coded. The doctor who injects the medicine only knows the type of medicine, and the information from the study is collected by another doctor who does not know the type of medicine.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan university of medical sciences

Street address

Anesthesiology group, Al-Zahra Educational and Medical Center, Soffe Boulevard, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8174675731

Approval date

2021-05-11, 1400/02/21

Ethics committee reference number

IR.MUI.MED.REC.1400.103

Health conditions studied

1

Description of health condition studied

Post operative pain

ICD-10 code

G89.18

ICD-10 code description

Other acute post procedural pain

2

Description of health condition studied

Post operative nausea and vomiting

ICD-10 code

K91.0

ICD-10 code description

Vomiting following gastrointestinal surgery

Primary outcomes

1

Description

Pain Visual Analogue Scale score

Timepoint
In recovery every 15 minutes and up to 24 hours after surgery every 6 hours
Method of measurement
Visual Analogue Scale score

Secondary outcomes

1

Description
Post operative nausea and vomiting Visual Analogue Scale score
Timepoint
In recovery every 15 minutes and up to 24 hours after surgery every 6 hours
Method of measurement
Visual Analogue Scale score

Intervention groups

1

Description
Intervention group 1: consists of 35 people receiving 100 mg of hydrocortisone who receive the drug once and as a preemptive by local infiltration at the site of laparoscopic cholecystectomy 15 minutes before the surgical incision is made.
Category
Treatment - Drugs

2

Description
Intervention group 2: consists of 35 people receiving 50 mg of hydrocortisone who receive the drug once and as a preemptive by local infiltration at the site of laparoscopic cholecystectomy 15 minutes before the surgical incision is made.
Category
Treatment - Drugs

3

Description
Control group: consists of 35 people receiving 20cc of non-drug normal saline (placebo)which is received as a preemptive by local infiltration at the surgical site of laparoscopic cholecystectomy15 minutes before the surgical incision is made.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Dr. Mohammadreza Safavi
Street address
Al-Zahra Educational and Medical Center, Soffe Boulevard, Isfahan
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Isfahan
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2

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Shaghayegh Haghjoo Javanmard
Street address
Vice Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.
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Postal code
81746-73461
Phone
+98 31 3668 8138
Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Safavi

Position

Professor of Anesthesiology

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