

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of the principles of the Modified Program of enhanced Recovery (ERAS) in ambulatory laparoscopic cholecystectomy in comparison with the traditional method and its effect on the quality of life of patients

Protocol summary

Study aim

Evaluating the effect of using ERAS principles in outpatient laparoscopic cholecystectomy outpatient surgeries in comparison with traditional methods and its effect on patients' quality of life

Design

Clinical trial with control group, parallel group, randomized 80 patients

Settings and conduct

Surgery ward of sina hospital of Tehran University of Medical Sciences during the year 1400

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. All patients (18-75) years who have accepted the consent and are candidates for elective cholecystectomy, do not have acute cholecystitis or gangrene. 2. Patients with a history of biliary colic. 3. Class 1 to 2 ASA anesthesia 4. Absence of jaundice and evidence of CBD stones 5. No kidney or liver or transplant failure 6. Absence of heart failure (EF <20%) 7. No uncontrolled blood pressure or diabetes 8. No history of upper abdominal surgery 9. No pregnancy 10. Do not use opioids or opioid antagonists in 90 days before Exclusion criteria :) 1. Emergency surgery 2. Lack of access to the patient 3. Convert laparoscopic surgery to open surgery 4. Patient dissatisfaction with continued participation in the study

Intervention groups

The intervention group includes patients who undergo the ERAS protocol and use non-opioid analgesia to control pain, while the control group uses opioids to control pain and do not receive ERAS.

Main outcome variables

Pain control, nausea and vomiting, length of hospital stay after surgery, readmission, quality of life of patients, satisfaction and complications after surgery in the intervention group compared to the control group based

on age, sex and type of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201113049373N3**

Registration date: **2021-11-01, 1400/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-01, 1400/08/10**

Update count: **0**

Registration date

2021-11-01, 1400/08/10

Registrant information

Name

Ehsan Rahimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4443 5556

Email address

dr.rahimpour83@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of the principles of the Modified Program of enhanced Recovery (ERAS) in ambulatory laparoscopic cholecystectomy in comparison with the traditional method and its effect on the quality of life of patients

Public title

Evaluation of the effect of the principles of the Modified Program of enhanced Recovery (ERAS) in ambulatory laparoscopic cholecystectomy in comparison with the traditional method and its effect on the quality of life of patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients (18-75) years who have accepted the consent and are candidates for elective cholecystectomy, do not have acute cholecystitis or gangrene Patients with a history of biliary colic. Class 1 to 2 ASA anesthesia Absence of jaundice and evidence of CBD stones Absence of renal or hepatic or transplant failure Absence of heart failure (EF <20%) No uncontrolled blood pressure or diabetes No history of upper abdominal surgery No pregnancy Do not use opioids or opioid antagonists in 90 days before

Exclusion criteria:

Emergency surgery No access to the patient Convert laparoscopic surgery to open surgery Patient dissatisfaction with continued participation in the study

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomization based on blocking of quadruple numbers used variable blocks that was easy method and equation of Groups. Samples divided to A and B that there was Six type : AABB, ABAB, ABBA, BBAA, BABA, BAAB

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**

Tehran University of Medical Sciences

Street address

Sina Hospital, 30 tir street, Imam Khomeini street

City

Tehran

Province

Tehran

Postal code

1134667911

Approval date

2021-10-01, 1400/07/09

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.794

Health conditions studied**1****Description of health condition studied**

Chronic cholecystitis and symptomatic biliary colic

ICD-10 code

K81.1

ICD-10 code description

Chronic cholecystitis

Primary outcomes**1****Description**

Evaluation of the effect of the principles of the Modified Program of enhanced Recovery (ERAS) in ambulatory laparoscopic cholecystectomy in comparison with the traditional method and its effect on the quality of life of patients

Timepoint

2,6,12 ,24 hours after operation-3 days and 7 days after surgery

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients candidate cholecystectomy that received ERAS protocol.

Category

Treatment - Surgery

2**Description**

Control group: Patients did not receive ERAS protocol.

Category

Treatment - Surgery

Recruitment centers1**Recruitment center****Name of recruitment center**

Surgery ward of sina hospital

Full name of responsible person

Ehsan Rahimpour

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Sina Hospital, 30 tir street, Imam Khomeini street

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Email

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Rahimpour

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Not all data can be shared.

When the data will become available and for how long

6 months after publication

To whom data/document is available

All people

Under which criteria data/document could be used

All analysis are possible on the data.

From where data/document is obtainable

Dr.rahimpour83@yahoo.com 09123705047

What processes are involved for a request to access data/document

The request will be sent within about 2 weeks.

Comments