Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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 devided 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 recevied ERAS protocol.

Category
Treatment - Surgery

2

Description
Control group: Patients did not receive ERAS protocol.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Surgery ward of sina hospital
Full name of responsible person
Ehsan Rahimpour
Street address
Sina Hospital, 30 tir street, Imam Khomeini street
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ehsan Rahimpour
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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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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
Ehsan Rahimpour

Position
Assistant professor

Latest degree
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Other areas of specialty/work
General Surgery

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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