

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of local marcaine (port location) with intraperitoneal marcaine on pain after laparoscopic cholecystectomy

Protocol summary

Study aim

Comparison of the effect of local marcaine (site of ports) with intraperitoneal marcaine on pain after laparoscopic cholecystectomy surgery.

Design

Clinical trial without control group, with parallel groups, one-sided blind, randomized, phase 2-3 on 28 patients, rand function of Excel software was used for randomization.

Settings and conduct

Patients in Aria Hospital of Mashhad will be randomly divided into two groups with the help of sealed envelopes: Group 1: Local infiltration (port site) of 20 ml of 0.25% bupivacaine solution at the end of the procedure before closing the wound, which will be 5 ml per port. Group 2: After removing the gallbladder, they will receive intraperitoneal infiltration of 20 ml of 0.25% bupivacaine solution in the bed of the gallbladder and under the right dome of the diaphragm.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1- Patients undergoing elective laparoscopic head cystectomy surgery 2- Age between 18 and 65 years Exclusion criteria: 1- The occurrence of unwanted complications during the operation 2- People with contraindications to the prescription of anesthetic drugs or opioids (patients with known hypersensitivity to the compounds of various anesthetic drugs)

Intervention groups

Group 1: Local infiltration (port site) of 20 ml of 0.25% bupivacaine solution at the end of the procedure before closing the wound, which will be 5 ml per port. Group 2: After removing the gallbladder, they will receive intraperitoneal infiltration of 20 ml of 0.25% bupivacaine solution in the bed of the gallbladder and under the right dome of the diaphragm.

Main outcome variables

1- Postoperative pain is different in the two study groups.
2- The amount of additional pain relief after the operation is different in the two study groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230526058293N1**

Registration date: **2023-05-31, 1402/03/10**

Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**

Update count: **0**

Registration date

2023-05-31, 1402/03/10

Registrant information

Name

Shabnam Shafiee jafarabad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3867 2305

Email address

shbnmshafiee@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of local marcaine (port location) with intraperitoneal marcaine on painafter laparoscopic cholecystectomy		Secondary Ids
		empty
Public title	Comparison of the effect of local marcaine (port location) with intraperitoneal marcaine on painafter laparoscopic cholecystectomy	Ethics committees
Purpose	Treatment	<u>1</u>
Inclusion/Exclusion criteria		Ethics committee
Inclusion criteria:	Patients undergoing elective laparoscopic head cystectomy surgery Age between 18 and 65 years	Name of ethics committee
Exclusion criteria:		Research Ethics Committee of Islamic Azad University, Mashhad.
Age	From 18 years old to 65 years old	Street address
Gender	Both	Mashhad, Imam Khomeini Boulevard, Bazarche Sarab, between 13 and 15 Bazarche Sarab
Phase	2-3	City
Groups that have been masked		mashhad
	Participant	Province
Sample size	Target sample size: 28	Razavi Khorasan
Randomization (investigator's opinion)	Randomized	Postal code
Randomization description	Patients will be randomly divided into two groups with the help of sealed envelopes Group 1: Local infiltration (port site) of 20 ml of 0.25% bupivacaine solution at the end of the procedure before closing the wound, which will be 5 ml per port. Group 2: After removing the gallbladder, they will receive intraperitoneal infiltration of 20 ml of 0.25% bupivacaine solution in the bed of the gallbladder and under the right dome of the diaphragm.	9187147578
Blinding (investigator's opinion)	Single blinded	Approval date
Blinding description	This study will be conducted in the form of a two-group, single-blind clinical trial, where the patients will be unaware of the assigned treatment, on patients undergoing elective laparoscopic cephalocystectomy surgery at Aria Hospital in Mashhad. People with entry criteria and those without exit criteria will enter the study after providing an explanation about the design and completing the informed consent form. Patients will be randomly divided into two groups with the help of sealed envelopes Group 1: Local infiltration (port site) of 20 ml of 0.25% bupivacaine solution at the end of the procedure before closing the wound, which will be 5 ml per port. Group 2: After removing the gallbladder, they will receive intraperitoneal infiltration of 20 ml of 0.25% bupivacaine solution in the bed of the gallbladder and under the right dome of the diaphragm.	2022-10-01, 1401/07/09
Placebo	Not used	Ethics committee reference number
Assignment	Parallel	129.IR.IAU.MSHD.REC.1401
Other design features		
		Health conditions studied
		<u>1</u>
		Description of health condition studied
		Comparison of the effect of local marcaine (port location) with intraperitoneal marcaine on painafter laparoscopic cholecystectomy
		ICD-10 code
		ICD-10 code description
		Primary outcomes
		<u>1</u>
		Description
		The amount of pain after the operation
		Timepoint
		4-8-24 hour
		Method of measurement
		Visual Analogue Scale
		Secondary outcomes
		empty
		Intervention groups
		<u>1</u>
		Description
		Intervention group Group 2: After removal of the gallbladder, intraperitoneal infiltration of 20 ml of 0.25% bupivacaine solution in the bed of the gallbladder and under the right dome of the diaphragm.
		Category

Treatment - Surgery

2

Description

Control group: Intervention group: Group 1: local infiltration (port site) of 20 ml of 0.25% bupivacaine solution at the end of the operation before closing the wound

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Aria hospital mashhad

Full name of responsible person

Dr.Hamed beyzaee

Street address

Mashhad - Jahanbani Street - Eastern Golestan Crossroads

City

mashhad

Province

Razavi Khorasan

Postal code

9187147578

Phone

+98 51 3222 9098

Email

nfo@aria-hospit.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Tooraj zandbaf

Street address

East golestan st 4, mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9187147578

Phone

+98 51 3222 9096

Email

nfo@aria-hospital.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Shabnam shfreejafarabad

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No 29 . daneshamooz st 6, mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9188869864

Phone

+98 51 3768 2305

Email

shbnmshafiee@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad javad ghamari

Position

Medical doctor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

East golestan5 , mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9187147578

Phone

+98 51 3222 9096

Email

ghamarimj@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shabnam shafiee jafarabad

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No 29, daneshamooz st 6, mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9188869864

Phone

+98 51 3768 2305

Email

shbnmshafiee@gmail.com

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