

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of intraperitoneal saline with bupivacaine in addition pulmonary recruitment maneuver on post-laparoscopic shoulder pain; a randomized double-blind clinical trial

Protocol summary

Study aim

Comparison of Saline with Bupivacaine intraperitoneally with Pulmonary Recurrence maneuver on shoulder pain after laparoscopy; A randomized double-blind clinical trial study

Design

Randomized clinical trial in individuals aged 20 to 60 years and with inclusion criteria, candidate cholecystectomy laparoscopic be carried out which has randomly divided into two groups of 40 people using block Rndvmyzshn were divided .

Settings and conduct

Anesthesia will be the same in all patients and laparoscopic surgery was performed by a skilled surgeon. In the first group, the end of the operation, in addition to the usual method of venting CO₂, normal saline solution heated to 20 cc per kg in supine position can be injected into the abdominal cavity (13). In addition to the serum injection, a pulmonary maneuver was performed by an anesthesiologist. In the second group, at the beginning, starting with surgery, 50 cc of bupivacaine diluted solution will be injected into the abdomen 25/0 percent of the space. At the end of the operation, a pulmonary recruitment maneuver was performed. Evaluation of shoulder pain and wound pain by visual analog scale pain gauges at time intervals: recovery, 12, 24 and 48 hours after surgery.

Participants/Inclusion and exclusion criteria

Age between 20 and 60 years, grade 1 and 2 physical classification according to the American Anesthesia Association Guideline, no drug addiction, no chronic pain, no anesthesia, history of disease and surgery in Shoulder and chest area and no abdominal surgery, women are not pregnant, no neurological and mental illness

Intervention groups

Group two intervention: Saline with Pulmonary Recurrence maneuver and Bupivacaine intraperitoneally

with Pulmonary Recurrence maneuver

Main outcome variables

the pain Intraperitoneal injection of saline and bupivacaine Pulmonary recruitment maneuver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190113042346N2**

Registration date: **2020-12-18, 1399/09/28**

Registration timing: **prospective**

Last update: **2020-12-18, 1399/09/28**

Update count: **0**

Registration date

2020-12-18, 1399/09/28

Registrant information

Name

hosnieh raufiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3657 6830

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of intraperitoneal saline with bupivacaine in addition pulmonary recruitment maneuver on post-laparoscopic shoulder pain; a randomized double-blind clinical trial

Public title
Comparison of intraperitoneal saline with bupivacaine in addition pulmonary recruitment maneuver on post-laparoscopic shoulder pain; a randomized double-blind clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 20 and 60 years Grade 1 and 2 physical classification according to the American Anesthesia Association Guideline No drug addiction No chronic pain Lack of sensitivity to anesthetics History of disease and surgery in Shoulder and chest area and no abdominal surgery Women are not pregnant No neurological and mental illness
Exclusion criteria:
 Conversion of laparoscopic surgery to laparotomy Creating any clinical condition in which pulmonary maneuver can not be performed Any complication that increases postoperative pain

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling in this study will be that first in order to enter patients in the study will be non-random sampling of the type "available" and then divide them into two intervention groups as randomized blocking using a web-based system Random blocking will be done at www.randomization.com

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and pain assessor did not know the type of intervention

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of North Khorasan University of Medical Sciences

Street address

Shahriar Street

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Bojnourd

Province

North Khorasan

Postal code

9678694176

Approval date

2020-08-26, 1399/06/05

Ethics committee reference number

IR.NKUMS.REC.1399.048

Health conditions studied

1

Description of health condition studied

Shoulder Pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Recovery, 12, 24 and 48 hours after surgery

Method of measurement

Pain assessment based on Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Saline group with Pulmonary Recruitment maneuver

Category

Treatment - Other

2

Description

Intervention group2 : Bupivacaine with Pulmonary
Recruitment maneuver

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Javad Shahinfar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology of North
Khorasan University of Medical Sciences

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research@nkums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Javad Shahin far

Position

Faculty member

Latest degree

Specialist

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**Person responsible for scientific
inquiries**

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be published after collection

When the data will become available and for how long

6 months after publication

To whom data/document is available

Researchers

Under which criteria data/document could be used

It can be used if citation is mentioned

From where data/document is obtainable

Scientific Officer

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

Send E-mail

Comments