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 Rndvmyzyshn 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)

Phone
+98 51 3657 6830

Email address
h.raufyian@gmail.com

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

City

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
Street address
Street
City
Bojnourd
Province
North Khorasan
Postal code
9417694734
Phone
+98 58 3229 7010
Email
h.raufyian@gmail.com

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
Street address
Shahriar Street
City
bojnourd
Province
North Khorasan
Postal code
9678694176
Phone
+98 58 3229 7182
Email
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
Other areas of specialty/work
Anesthesiology
Street address
Shahriar Street
City
Bojnourd
Province
North Khorasan
Postal code
9678694176
Phone
009832297096
Email
h.raufyian@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Hosnieh Raufiyan
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Shahriar Street
City
Bojnourd
Province
North Khorasan
Postal code
9678694176
Phone
+98 58 3229 7096
Email
h.raufyian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Bojnourd University of Medical Sciences

Full name of responsible person
Hosnieh Raufiyan

Position
Faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Shahriar Street

City
Bojnourd

Province
North Khorasan

Postal code
9678694176

Phone
+98 58 3229 7096

Email
h.raufyian@gmail.com

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