Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of intraperitoneal normal saline infusion and the pulmonary recruitment maneuver to reduce postlaparoscopic shoulder and upper abdominal pain in elective gynecologic surgeries

Protocol summary

Summary

The study was designed as a randomized, controlled, clinical trial to estimate the effectiveness of pulmonary recruitment maneuver and intraperitoneal normal saline infusion on reducting postlaparoscopic shoulder and upper abdominal pain and surgical pain. A total of 280 patients scheduled for elective laparoscopic surgeries were randomly divided in four groups: pulmonary recruitment maneuver, intraperitoneal normal saline infusion, combination of pulmonary recruitment maneuver and intraperitoneal normal saline infusion, and control group with no intervention. The primary endpoint of this study was postlaparoscopic upper abdominal pain, shoulder pain and surgical pain as measured by a visual analogue scale (VAS).Visual analogue scale ratings were obtained at recovery, 2, 6,12 and 24 hours postoperatively. secondary outcome measures included the occurrence of nausea or vomiting and abdominal distention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402022576N8**
Registration date: **2014-05-05, 1393/02/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-05, 1393/02/15

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-04-01, 1393/01/12

Expected recruitment end date

2015-03-31, 1394/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of intraperitoneal normal saline infusion and the pulmonary recruitment maneuver to reduce postlaparoscopic shoulder and upper abdominal pain in elective gynecologic surgeries

Public title

The effectiveness of intraperitoneal normal saline infusion and the pulmonary recruitment maneuver to reduce postlaparoscopic shoulder and upper abdominal pain in elective gynecologic surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

The patients selected for screening were all required laparoscopic surgery during the study period. The

inclusion criteria were female gender, age 20–65 years old; an American Society of Anesthesiologists physical status classification of I or II, and a willing to undergo laparoscopic surgeries for benign gynecologic lesions, including laparoscopically assisted vaginal hysterectomy, myomectomy, and cystectomy. Patients were excluded from randomization if their disease was malignant, or if they were unwilling to participate.

Age
From **20 years** old to **65 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **280**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The etic commitee of Tehran university of medical sciences

Street address
Faculty of medicine-Ebnesina avenue-Keshavarz street-

City
Tehran

Postal code

Approval date
2014-02-04, 1392/11/15

Ethics committee reference number
9111290011

Health conditions studied

1

Description of health condition studied
Laparoscopy

ICD-10 code
N99

ICD-10 code description
Postprocedural disorders of genitourinary system, not elsewhere classified

Primary outcomes

1

Description
Post operative pain

Timepoint
2, 4, 6, 12, 24 hours after surgery

Method of measurement
VAS analouge

Secondary outcomes

1

Description
Nausea

Timepoint
24 hours after surgery

Method of measurement
Questionaire

2

Description
Vomiting

Timepoint
24 hours after surgery

Method of measurement
Questionaire

3

Description
Abdominal distention

Timepoint
24 hours after surgery

Method of measurement
Questionaire

Intervention groups

1

Description
Intervention1: pulmonary recruittment manuver,deep respiration by anesthesiologist is done at the end of surgery

Category
Prevention

2

Description
Intervention2:intraperitoneal normal salin ,150ml in upper abdomen is left

Category
Prevention

3

Description
Intervention3:Pulmonary recruitment manuver+intraperitoneal salin
Category
Prevention

4

Description
Control : No intervention
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Women Hospital
Full name of responsible person
Dr.Davari
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Tehran university of medical sciences
Full name of responsible person
Miss Moamaei
Street address
Central building of Tehran university of medical sciences-fifth floor-Keshavarz Blvd
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Tehran university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Phone
00
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty