

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 reducing 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 ethic committee 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

Tehran University of Medical Sciences

Full name of responsible person

Fateme Davari Tanha

Position

Associate professor

Other areas of specialty/work

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Other areas of specialty/work

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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