

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of manual maneuver on shoulder pain of laparoscopic gynecology surgery

Protocol summary

Study aim

Determining the effect of manual maneuver on shoulder pain of laparoscopic surgery

Design

This phase 3 clinical trial with a control group, with parallel groups, non-blinding, randomized using the Random allocation rule is performed on 80 patients.

Settings and conduct

This randomized clinical trial study will be performed on 80 women candidates for gynecological laparoscopic surgery in Yas Hospital. The sampling method is a convenience method.

Participants/Inclusion and exclusion criteria

Inclusion criteria include women candidates for gynecological laparoscopic surgery in the age group of 18 to 60 years. Criteria for not entering: Conversion of the surgery to laparotomy and Body mass index > 40.

Intervention groups

After the surgery, in the intervention group, the abdomen CO₂ gas is evacuated through two-handed massage in the entire thickness of the abdomen towards the umbilical and suprapubic trocar, while in the control group, the abdomen CO₂ gas is evacuated in a traditional and passive way by opening the outlet of the umbilical and suprapubic trocar.

Main outcome variables

Measurement of shoulder pain three times, 6, 24 and 48 hours after surgery using a visual analog scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049169N4**

Registration date: **2023-03-28, 1402/01/08**

Registration timing: **prospective**

Last update: **2023-03-28, 1402/01/08**

Update count: **0**

Registration date

2023-03-28, 1402/01/08

Registrant information

Name

Elham Feizabad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8608 9092

Email address

elhamfeizabad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of manual maneuver on shoulder pain of laparoscopic gynecology surgery

Public title

The effect of manual maneuver on shoulder pain of laparoscopic surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for gynecological laparoscopic surgery

Exclusion criteria:
Conversion of the surgery to laparotomy Body mass index> 40

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation rule: First, 40 letters A and 40 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A or B are determined by a lot.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Tehran University of medical sciences

Street address
Deputy of research, sixth floor of central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1598718311

Approval date
2022-02-12, 1400/11/23

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1308

Health conditions studied

1

Description of health condition studied

Pain in shoulder

ICD-10 code

M25.51

ICD-10 code description

Pain in shoulder

Primary outcomes

1

Description

shoulder pain

Timepoint

Three times, 6, 24 and 48 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the surgery, the abdomen CO2 gas is evacuated through two-handed massage in the entire thickness of the abdomen towards the umbilical and suprapubic trocar.

Category

Prevention

2

Description

Control group: After the surgery, the abdomen CO2 gas is evacuated in a traditional and passive way by opening the outlet of the umbilical and suprapubic trocar.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Elham Feizabad

Street address

Yas Hospital, Next to the Sarv street , North Nejatollahi street ,Karimkhan avenue.

City

Tehran

Province

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1597856511
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+98 21 8608 9089
Fax
Email
elhamfeizabad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Fotouhi
Street address
Vice-Dean of Research of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.
City
Tehran
Province
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Postal code
1416634793
Phone
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Email
vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Elham Feizabad
Position
Community Medicine Specialist
Latest degree
Specialist

Other areas of specialty/work

Public Health/Community Medicine

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Yas Hospital, Next to the Sarv street , North Nejatollahi street ,Karimkhan avenue.

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified participants

When the data will become available and for how long

After manuscript published

To whom data/document is available

No limitations

Under which criteria data/document could be used

The data is only available to the project manager, Dr. Elham Feizabad, and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Elham Feizabad

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

Any request must be made in writing and sent through email.

Comments