Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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+98 21 8608 9092
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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.

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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.
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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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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