

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of drain hemovac on shoulder pain after women laparoscopic surgery and compared with deep breathing technique

Protocol summary

Study aim

The aim of this study was to determine the effect of drainage on the Hemovac drain and deep breathing technique on the amount of shoulder pain in female patients undergoing laparoscopic surgery.

Design

The clinical trial included three groups: two intervention groups and one control group, each with a sample size of 33, community based and pragmatic, with parallel, blind, randomized groups

Settings and conduct

The aim of this study was to determine the effect of using drann in women's laparoscopic surgery on postoperative pain and its comparison with deep breathing technique. This study is a randomized, non-controlled clinical trial. Inclusion criteria include: Diagnostic laparoscopy, myomectomy and cystectomy. In the drain group, laparoscopic surgery is performed routinely. Then a hemovacum duct with a closed system is embedded in the subtrochic site and is removed from the drainage section before discharge. In the deep breathing group, the person is asked to slowly breathe deeply after three hours of laparoscopic surgery every hour. In a non-drainage group, only laparoscopic surgery is performed routinely. The severity of abdominal pain and shoulder is measured at 3, 6, 12 and 24 hours after visual acuity. After surgery, Diclofenac Suppository is prescribed every 12 hours in case of pain and then the pain and dosage of suppository and surgical complications are compared in three groups.

Participants/Inclusion and exclusion criteria

Entry criteria for non-use of analgesic drugs and lack of surgical history : Exit criteria have had shoulder, abdomen, pelvic before surgery

Intervention groups

Control group 1 the effect of drainage with Hemovac drain on shoulder pain . Control group 2 the effect deep breathing on shoulder pain after laparoscopic surgery in women.Third control group without any intervention.

Main outcome variables

Score of shoulder pain : pain in surgical site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190113042347N1**

Registration date: **2019-03-16, 1397/12/25**

Registration timing: **retrospective**

Last update: **2019-03-16, 1397/12/25**

Update count: **0**

Registration date

2019-03-16, 1397/12/25

Registrant information

Name

Fatemeh Hosseinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-01, 1397/12/10

Expected recruitment end date

2019-09-01, 1398/06/10

Actual recruitment start date

2018-04-30, 1397/02/10

Actual recruitment end date

2018-12-22, 1397/10/01

Trial completion date

2019-01-30, 1397/11/10

Scientific title

The effect of drain hemovac on shoulder pain after women laparoscopic surgery and compared with deep breathing technique

Public title

The effect of drain hemovac on shoulder pain after women laparoscopic surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete consciousness No use of pain medication
Hemodynamic stability The first surgery under general anesthesia

Exclusion criteria:

Taking memory medication Having shoulder, abdomen, pelvic pain before surgery

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **99**

Actual sample size reached: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

To determine the groups, the Block Randomization method is used to determine the groups in the six-block blocks and then determine the situation randomly to determine the final volume of the samples .

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in the research do not know which investigation groups are located. Health care personnel do not know which patients are in investigation groups are located.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

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Farah Abad Road,Sari , Mandarin Province

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sari

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Postal code

48157-33971

Approval date

2019-02-05, 1397/11/16

Ethics committee reference number

IR.MAZUMS.REC.1397.300

Health conditions studied**1****Description of health condition studied**

shoulder pain

ICD-10 code

M25.51

ICD-10 code description

Pain in shoulder

2**Description of health condition studied**

Abdominal pain

ICD-10 code

R10.8

ICD-10 code description

Other abdominal pain

Primary outcomes**1****Description**

Shoulder pain

Timepoint

At 3, 6, 12, 24 hours after the end of laparoscopic surgery

Method of measurement

Visual Analogue Scale

2**Description**

Abdominal pain

Timepoint

At 3, 6, 12, 24 hours after the end of laparoscopic surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Taking analgesic drugs

Timepoint

end of surgery

Method of measurement

check list

2

Description

Nausea

Timepoint

End of surgery

Method of measurement

check list

Intervention groups

1

Description

Intervention group 1: In the drain group, laparoscopic surgery is performed routinely. A hemovacuum duct is then inserted with a closed system from the truce subunit and leaves the morning of the next laparoscopy.

Category

Prevention

2

Description

Intervention group 2 : In the deep breathing group, laparoscopic surgery is performed routinely. After the surgery, the patient breathes deeply up to three times a day.

Category

Prevention

3

Description

Control group: Only laparoscopic surgery is done routinely.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Hospital, Urmia

Full name of responsible person

Fatemeh Hosseinzadeh

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Shahid Motahari Hospital, Kashani St , Urmia , West Azerbaijan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Hosseinzadeh

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available