

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of drain effect on postoperative pain in laparoscopic gynecological surgery

Protocol summary

Summary

The aim of this study is the assessment of drain effect on postoperative pain in laparoscopic gynecological surgeries. This study is a randomized, non-placebo-controlled, single-center clinical trial. Inclusion criteria is all women aged 20- 55 years old who are candidates for laparoscopic cystectomy, total hysterectomy and myomectomy. In case of malignancies and any complication such as massive bleeding, bladder and genitourinary injuries during and after the surgery, patients will be excluded from the study. In intervention group (drain group), the surgery will be performed routinely. Then, a closed system of hemovacuum drain will be embedded from subsidiary truca and will be brought out the next day. In non drain group, just the laparoscopic surgery will be done routinely. The amount of abdominal and shoulder pain will be measured 12 and 24 hours after the surgery using visual analog scale. After the surgery, Panthazocin will be administered for patients with the pain number of more than 6 .If necessary, non steroid anti inflammatory drugs will be injected for those with pain number under 6. Pain amount, using antibiotics and surgery complications will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022316161N2**

Registration date: **2016-03-02, 1394/12/12**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-02, 1394/12/12

Registrant information

Name

Reyhaneh Hosseini

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences

Expected recruitment start date

2016-03-03, 1394/12/13

Expected recruitment end date

2016-06-02, 1395/03/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of drain effect on postoperative pain in laparoscopic gynecological surgery

Public title

Assessment of drain effect on pain after laparoscopic surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age of 20- 55; candidates of laparoscopic cystectomy; total hysterectomy; myomectomy
Exclusion criteria: presence of malignancy in pathology results; surgery complications during and

after the surgery such as massive bleeding; bladder injury; genitourinary injury

Age

From **20 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tehran University of Medical Sciences

Street address

Qods St, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2016-02-20, 1394/12/01

Ethics committee reference number

IR.TUMS.REC.1394.2012

Health conditions studied

1

Description of health condition studied

abdominal pain

ICD-10 code

R10.4

ICD-10 code description

Other and unspecified abdominal pain

2

Description of health condition studied

shoulder pain

ICD-10 code

M75.9

ICD-10 code description

Shoulder lesion, unspecified

Primary outcomes

1

Description

abdominal and shoulder pain

Timepoint

6- 12 hours after surgery

Method of measurement

visual analog scale

Secondary outcomes

1

Description

fever

Timepoint

after surgery

Method of measurement

termometer

2

Description

using antibiotic

Timepoint

after surgery

Method of measurement

check list

Intervention groups

1

Description

In drain group, laparoscopic surgery is done routinely. Then a closed hemovacuum drain system is embedded from subsidiary truca and will be brought out the next day.

Category

Prevention

2

Description

In control group, just the laparoscopic surgery is performed.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Hospital

Full name of responsible person

Reyhaneh Hosseini

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Full name of responsible person

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences , Deputy of Research

Full name of responsible person

Dr.Masood Yunesian

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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

Tehran University of Medical Sciences , Deputy of Research

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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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