Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Surgical and Patient Outcomes Using Normal Saline Enema for Bowel Preparation Before Benign Gynecologic Laparoscopic Surgeries

Protocol summary

Study aim

Evaluating surgical and patient Outcomes Using Normal Saline Enema for Bowel Preparation Before Benign Gynecologic Laparoscopic Surgeries

Design

This is a randomized, single-blind, single-center clinical trial with parallel groups on 112 patients. The rand function of the Excel software was used for randomization.

Settings and conduct

This study is performed in Arash hospital on 112 female patients candidates for level2 and 3 laparoscopic surgery aged 18-65 years. Patients are randomly divided into two groups of enema before surgery and without enema. The physician will check the outcome will be blind from the study is used to analyze the data. Due to the type of study, the patient will not be blind in this study.

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Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients who are candidates for level 2 and 3 laparoscopic gynecologic surgeries Exclusion criteria: Patients who are at risk for intestinal injury during laparoscopy and are candidates for complete bowel preparation before surgery such as: a history of multiple previous surgeries with many adhesion, severe endometriosis in cul de sac and bowel/large uterus with adhesion in hysterectomy, cancer surgery, surgery in sever PTD with abcess. Patients who are candidates for level 1 laparoscopic surgeries such as TL and diagnostic laparoscopy. Patients who are candidates for level 4 laparoscopy surgeries such as lymphadenectomy,severe endometriosis, presacral neurectomy History of patients intestinal diseases such as IBS and colitis Severe obesity (BMI>35)

Intervention groups

Intervention for this group is enema with normal saline once at 11 pm (the night before the operation) and once at 6 am in the morning of the operation. Control group: without intervention.

Main outcome variables

surgeon's satisfaction from intraoperative visualization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110530006640N6**
Registration date: **2020-07-21, 1399/04/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-21, 1399/04/31**
Update count: **0**

Registration date

2020-07-21, 1399/04/31

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-20, 1399/04/30

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Surgical and Patient Outcomes Using Normal Saline Enema for Bowel Preparation Before Benign Gynecologic Laparoscopic Surgeries

Public title

Surgical outcomes using bowel enema before benign gynecologic laparoscopic surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for level 2 and 3 laparoscopic gynecologic surgeries

Exclusion criteria:

Patients who are at risk for intestinal injury during laparoscopy and are candidates for complete bowel preparation before surgery such as : a history of multiple previous surgery with many adhesion, sever endometriosis in cul de sac and bowel/large uterus with adhesion in hysterectomy,cancer surgery, surgery in sever PTD with abcess. Patients who are candidates for level 1 laparoscopic surgeries such as TL and diagnostic laparoscopy. Patients who are candidates for level 4 laparoscopy surgeries such as lymphadenectomy,sever endometriosis, presacral neurectomy History of patients intestinal diseases such as IBS and colitis Severe obesity (BMI>35)

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation methods were blocks that were designed by the epidemiologist using version 13 Stata software. The number of blocks is 6. The random allocation list of patients is only at the disposal of the clinic nurse.To hide the random allocation process, 112 treatment cards written in order. The cards are placed in sealed envelopment. When the physician determined that patient is eligible to enter the study, the nurse provides the physician with an envelope related to the type of intervention for check of the outcome, the commenting physician is unaware of the type of intervention. A statistical expert who is separated from the study is used to analyze the data. Due to the type of study, the patient will not be blind in this study.

Blinding (investigator's opinion)

Double blinded

Blinding description

for evaluating the outcomes, The physician is unaware of the type of intervention. A statistical expert who is separated from the study is used to analyze the data. Due to the type of study, the patient will not be blind in this study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Research and Technology Dept, Sixth Floor of Central University Building, Corner of Quds Street, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-03-04, 1398/12/14

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.944

Health conditions studied

1

Description of health condition studied

Benign gynecology disease

ICD-10 code

N85

ICD-10 code description

Other noninflammatory disorders of uterus, except cervix

Primary outcomes

1

Description

Surgeon's satisfaction from intraoperative visualization and bowel handling

Timepoint

Immediately after surgery

Method of measurement

Questionnaire

2

Description
Complication of surgery such as viscoralinjury , fever, decrease of hemoglobin
Timepoint
Intraoperative and after surgery
Method of measurement
Patient File

Secondary outcomes

1

Description
Duration of surgery
Timepoint
End of surgery
Method of measurement
Cornometer

2

Description
Duration of hospitalization
Timepoint
Time of the discharge from the hospital
Method of measurement
Day/Patient file

Intervention groups

1

Description
Intervention group:Patients eat light meals and fluids the night before surgery and they become NPO from 12 midnight . Intervention for this group is enema with normal saline once at 11 pm (the night before the operation) and once at 6 am in the morning of operation.
Category
Treatment - Other

2

Description
Control group:Patients eat light meals and fluids the night before surgery and they become NPO from 12 midnight
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Women Hospital
Full name of responsible person
Dr.Zahra Asgari
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Arash Women 's Hospital, Eastern 162th St, Baghdarnia st, Resalat Highway, Tehranpars, Tehran ,Iran.
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Sponsors / Funding sources

1

Sponsor
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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
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
Dr Zahra Asgari
Position
Associate professor
Latest degree
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Person responsible for updating data

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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