

# 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 randomization 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 level 2 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.

##### 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 adhesions, severe endometriosis in cul de sac and bowel/large uterus with adhesion in hysterectomy, cancer surgery, surgery in severe PTB with abscess. 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

##### Name

Zahra Asgari

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7788 8755

##### Email address

asgariza@sina.tums.ac.ir

##### 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 viscoral injury , 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

**Street address**

Arash Women 's Hospital, Eastern 162th St, Baghdarnia st, Resalat Highway, Tehranpars, Tehran ,Iran.

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**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr.Sahraeian

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Qods St, Keshavarz Blvd

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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**

Dr Zahra Asgari

**Position**

Associate professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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Arash Hospital, Rashid street ,Resalat highway

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

Tehran University of Medical Sciences

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Dr Zahra Asgari

**Position**

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**Other areas of specialty/work**

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**Web page address****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