

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation of effect of intra peritoneal catheter insertion on post operation complications of pelvic and ovarian laparscopy

#### Protocol summary

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##### Summary

The purpose of this study is evaluation of effect of intraperitoneal catheter insertion on postoperation complications of lepvic and ovarian laparascopy in female patients. Patients who are in fertility age with benign gynecologic disease that indicated for laparascopy were included, and patients who are pregnant; have IBD or IBS; high grade fever; and patients who have active infectious disease were excluded. This RCT study is conducted on 100 patients. Patients randomly were divided in to intervention and control group and insreted catheter in case group for 24 hours, respectively the pain and GI complications in patients will be copmared and evaluated

##### Recruitment status

**Recruitment complete**

##### Funding source

Yasuj University of Medical Sciences

##### Expected recruitment start date

2017-01-19, 1395/10/30

##### Expected recruitment end date

2017-04-20, 1396/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017082335871N1**

Registration date: **2017-09-05, 1396/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-09-05, 1396/06/14

##### Registrant information

###### Name

Farid Moradian

###### Name of organization / entity

Yasuj University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 74 3323 3702

###### Email address

##### Scientific title

Evaluation of effect of intra peritoneal catheter insertion on post operation complications of pelvic and ovarian laparscopy

##### Public title

Effect of catheter on laparascopy post operation complications

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

all of patients are female in age of fertility with benign gynecologic disease that accepted to participate. exclusion criteria: refuse to participation;BD or IBS disease; pregnancy; infection; high grade fever; and manifestation of any unpredictable problem that interrupt laparascopy or catheter insertion

##### Age

From **15 years** old to **49 years** old

##### Gender

Female

##### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **100**

## 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

Ethics Committee of Yasuj University of Medical Science

##### Street address

Yasuj University of Medical Sciences, Motahari street, Yasuj city

##### City

Yasuj

##### Postal code

#### Approval date

2017-01-21, 1395/11/02

#### Ethics committee reference number

IR.YUMS.REC.1395.195

## Health conditions studied

### 1

#### Description of health condition studied

Complications of pelvic and ovarian laparoscopy

#### ICD-10 code

T88.8, T88

#### ICD-10 code description

Other specified complications of surgical and medical care, not elsewhere classified, Complication of surgical and medical care, unspecified

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

24 hours post operation

#### Method of measurement

visual scale

### 2

#### Description

nausea/vomiting

#### Timepoint

up to 48 hours post operation

#### Method of measurement

questionnaire

## Secondary outcomes

### 1

#### Description

start gass passing time,start defication time

#### Timepoint

up to 72 hours postoperation

#### Method of measurement

check list

### 2

#### Description

pain

#### Timepoint

one week

#### Method of measurement

visual scale

### 3

#### Description

pain

#### Timepoint

one month

#### Method of measurement

visual scale

### 4

#### Description

need for analgesic

#### Timepoint

48 hours post operation

#### Method of measurement

miligram

## Intervention groups

### 1

#### Description

in intervention groupintarperitoneal catheter will be inserted in cul de sac for 24 hours

#### Category

Treatment - Surgery

### 2

#### Description

in control group no catheter will be inserted

#### Category

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shahid Beheshti Hospital of Yasuj City

**Full name of responsible person**

Farid Moardian

**Street address**

Shahid Beheshti Hospital, Shahid Montazeri Street,  
Yasuj

**City**

Yasuj

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Yasuj University of Medical Sciences

**Full name of responsible person**

Hossein Mari Oryad

**Street address**

Yasuj University of Medical Sciences, Motahari street,  
Yasuj city

**City**

Yasuj

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yasuj University of Medical Sciences

**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**

Yasuj University of Medical Sciences

**Full name of responsible person**

Farid Moradian

**Position**

Associated Professor

**Other areas of specialty/work****Street address**

Shahid Mofateh Clinic, next to Shahid Beheshti  
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+98 74 3322 8212

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## 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*