

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### The effects of prophylactic appendectomy on outcome of therapeutic laparoscopy in patients with endometriosis

#### Protocol summary

##### Study aim

This study aimed to evaluate the impact of short term and mid-term prophylactic appendectomy during laparoscopic surgery in patients with endometriosis.

##### Design

This randomized double-blind clinical trial, including 56 female patients with endometriosis, candidates for laparoscopic surgery will take place in Hazrat e Rasool hospital-Tehran. individuals will be divided randomly using random digits table in two equal groups (n1=n2=28).

##### Settings and conduct

After obtaining written informed consent, both groups will receive a prophylactic antibiotic prior to the surgery and then under general anesthesia, the intervention will be performed. In the intervention group, the appendix will be removed prophylactically during laparoscopic surgery for endometriosis.

##### Participants/Inclusion and exclusion criteria

Patients with endometriosis, laparoscopic surgery candidates, no history of appendectomy, informed consent form included in the study. exclusion criteria were considered as gastrointestinal endometriosis, acute appendicitis, pelvic pain with etiology other than endometriosis, Failure to prove the presence of endometriosis in surgery, unwillingness to continue the study and abnormal anatomical placement of appendix.

##### Intervention groups

The first group will undergo appendectomy with laparoscopy surgery and the second group will exclusively undergo laparoscopy surgery without appendectomy. two groups will compare with each other regarding short term consequences (duration of surgery, Lost blood volume, duration of hospitalization, complications after surgery in the hospital, The need for admission of analgesics during hospitalization) and also mid-term consequences (complications of 6 months after surgery, mid-term admission or hospitalization).

##### Main outcome variables

Duration of hospitalization, lost blood volume, pain, fever, morbidity, histopathological findings in appendices

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150817023666N12**

Registration date: **2019-01-14, 1397/10/24**

Registration timing: **retrospective**

Last update: **2019-01-14, 1397/10/24**

Update count: **0**

##### Registration date

2019-01-14, 1397/10/24

##### Registrant information

##### Name

Abolfazl Mehdizadeh kashi

##### Name of organization / entity

Iran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 216651500

##### Email address

mehdizadeh.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-22, 1397/03/01

##### Expected recruitment end date

2018-12-22, 1397/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effects of prophylactic appendectomy on outcome of therapeutic laparoscopy in patients with endometriosis

**Public title**  
The effects of prophylactic appendectomy on short term and mid-term outcome of therapeutic laparoscopy in patients with endometriosis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having endometriosis Laparoscopic surgery candidates  
No history of appendectomy Informed consent to enter the study  
**Exclusion criteria:**  
Gastrointestinal endometriosis Having acute appendicitis  
Pelvic pain with pathology other than endometriosis  
Failure to prove the presence of endometriosis in surgery  
Unwillingness to continue the study Abnormal anatomical placement of appendix

**Age**  
No age limit

**Gender**  
Female

**Phase**  
2

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**  
Target sample size: 56

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Block randomization with blocks of size four will be used. Intervention and non-intervention groups allocation will be determined randomly with A or B and then all individuals in the two groups will be divided into the blocks using random digits.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Participants and data analyser are blinded of the allocation of study groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics committee of Iran University of Medical Science

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1986663311

**Approval date**

2018-01-23, 1396/11/03

**Ethics committee reference number**

IUMS.REC.1397.288

## Health conditions studied

### 1

#### Description of health condition studied

Appendectomy

**ICD-10 code**

R83-R89

**ICD-10 code description**

Abnormal findings on examination of other body fluids, substances and tissues, without diagnosis

## Primary outcomes

### 1

#### Description

Duration of hospitalization

**Timepoint**

During hospitalization after surgery and 6 months after surgery

**Method of measurement**

Medical file records and phone call

### 2

#### Description

Lost blood volume

**Timepoint**

During hospitalization after surgery and 6 months after surgery

**Method of measurement**

Blood test

### 3

#### Description

Pain

**Timepoint**

After surgery and 6 months after surgery

**Method of measurement**

Visual Analog Scale for Pain

#### 4

**Description**

Fever

**Timepoint**

After surgery and 6 months after surgery

**Method of measurement**

Thermometer

#### 5

**Description**

Morbidity

**Timepoint**

Short term and mid-term morbidity

**Method of measurement**

Questionnaire

### Secondary outcomes

#### 1

**Description**

Histopathological findings in appendices

**Timepoint**

After surgery

**Method of measurement**

Pathology report

### Intervention groups

#### 1

**Description**

In the intervention group, the appendix will be removed prophylactically during laparoscopic surgery for endometriosis.

**Category**

Treatment - Surgery

#### 2

**Description**

In control group laparoscopy without appendectomy will be performed.

**Category**

Treatment - Surgery

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Rasoul-e-Akram Hospital

**Full name of responsible person**

Abolfazal Mehdizadehkashi

**Street address**

Rasoul Akram Hospital, Satarkhan St, Tehran

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### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Vice Chancellor for Administration of Iran University of Medical Sciences (IUMS)

**Street address**

Iran University of Medical Sciences, Hemmat freeway, next to Milad tower, Tehran.

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ivco@iums.ac.ir

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Abolfazl Mehdizadehkashi

**Position**

Professor of Obstetrics and Gynecology

**Latest degree**

Subspecialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Elahé Afshari  
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## Person responsible for updating data

### Contact

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Abolfazl Mehdizadeh-kashi  
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**Latest degree**  
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**Other areas of specialty/work**  
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amehdizadehkashi@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Part of data like the main outcome or the same will be shared

### When the data will become available and for how long

Access after 6 months after publication

### To whom data/document is available

Data will be available for all researchers

### Under which criteria data/document could be used

limitless

### From where data/document is obtainable

For receiving data please be contacted with  
el\_afshari@yahoo.com

### What processes are involved for a request to access data/document

limitless

### Comments