

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)

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+98 216651500

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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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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

Iran University of Medical Sciences

Full name of responsible person

Elahe Afshari

Position

Fellowship

Latest degree

Specialist

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Person responsible for updating data

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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