

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Effect of laparoscopic surgery treatment on sexual dysfunction and quality of life in patients with deep infiltrative endometriosis

Protocol summary

Study aim

The purpose of this study was to evaluate the effect of laparoscopic surgical resection of endometriosis lesions in reducing the pain and dyspareunia and sexual quality of life of the individual.

Design

In this study, 30 patients with deep endometriosis who are eligible for inclusion in the study will be included. All patients will undergo laparoscopic surgery and only one group.

Settings and conduct

This study will be carried out on patients with deep endometriosis referring to the Department of Obstetrics and Gynecology Rasoul Akram Hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Married patients Hetrosexual Having sexual dysfunction in 6 months Early diagnosis of endometriosis and chronic pelvic pain associated with endometriosis Having informed consent for inclusion Lack of pelvic pain originating from other organs: Causes gastrointestinal, genitourinary The use of gonadotropins or other hormonal drugs in 3 months Lack of gynecologic malignancies The absence of ultrasound uterine fibroids before surgery no underlying disease, such as cardiovascular diseases, respiratory, renal, hematologic, hepatic, neurological, psychological, The patient is not pregnant. Exclusion criteria: Failure to prove the existence of endometriosis surgery Not wanting to continue the study

Intervention groups

This study is before and after, and all patients will undergo laparoscopic surgery.

Main outcome variables

Pain Quality of Life Female Sexual Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150817023666N8**

Registration date: **2018-01-28, 1396/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-28, 1396/11/08**

Update count: **0**

Registration date

2018-01-28, 1396/11/08

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

iran university of Medical science

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of laparoscopic surgery treatment on sexual dysfunction and quality of life in patients with deep

infiltrative endometriosis

Public title

Effect of laparoscopic surgery treatment on sexual dysfunction and quality of life in patients with deep infiltrative endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married patients Hetrosexual Having sexual dysfunction in 6 months Early diagnosis of endometriosis and chronic pelvic pain associated with endometriosis Having informed consent for inclusion Lack of pelvic pain originating from other organs: Causes gastrointestinal, genitourinary dont use of gonadotropins or other hormonal drugs in 3 months Lack of gynecologic malignancies The absence of ultrasound uterine fibroids before surgery no underlying disease, such as cardiovascular diseases, respiratory, renal, hematologic, hepatic, neurological, psychological The patient is not pregnant

Exclusion criteria:

Failure to prove the existence of endometriosis surgery Not wanting to continue the study Pregnancy

Age

From **20 years** old to **48 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Rasoul-e-Akram Hospital, Niayesh St, Sattarkhan St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2017-02-22, 1395/12/04

Ethics committee reference number

IR.IUMS.REC 1395.95-04-218-29916

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80.4

ICD-10 code description

Endometriosis of rectovaginal septum and vagina

Primary outcomes

1

Description

quality of life and sexul function

Timepoint

one year

Method of measurement

questionear

Secondary outcomes

1

Description

pain

Timepoint

one year

Method of measurement

questionear

Intervention groups

1

Description

laprascopic surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-e-Akram Hospital

Full name of responsible person

Abolfazi Mehdizadeh-Kashi

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Sponsors / Funding sources

1

Sponsor

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Iran University of Medical Sciences

Full name of responsible person

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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

Samaneh Rokhgireh

Position

Assistant Profesor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

All information except personal details

When the data will become available and for how long

After Publication of paper

To whom data/document is available

All

Under which criteria data/document could be used

more research

From where data/document is obtainable

Dr. Rokhgireh

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

Sending Email For Request Information

Comments