

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of surgery of endometriosis on fertility and it's complications in women with endometriosis

Protocol summary

Study aim

To evaluate the effect of surgery of endometriosis on fertility and it's complications in women with endometriosis

Design

In this study, 64 Women with endometriosis who complained of infertility and referred to Infertility Center of Besat Hospital in Sanandaj for treatment of infertility were included. Women with endometrium greater than 4 cm and aged 18 to 40 years who complained of infertility were included in the study and women with chronic internal diseases that had a definite need to surgery, as well as their infertility had other causes than endometrium were excluded from the study. Endometriosis surgery was performed for patients in the intervention group with an endometrium size of more than 4 cm. Endometriosis surgery was not performed for patients in the control group. Patients randomly selected based on quadruple blocks. In each group 32 women were studied.

Settings and conduct

The study site was Sanandaj city.

Participants/Inclusion and exclusion criteria

Women with endometrium greater than 4 cm and aged 18 to 40 years who complained of infertility were included in the study. Women with chronic internal diseases that had a definite need to surgery, as well as their infertility had other causes than endometrium were excluded from the study.

Intervention groups

Endometriosis surgery was performed for patients in the intervention group with an endometrium size of more than 4 cm. Endometriosis surgery was not performed for patients in the control group.

Main outcome variables

Pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012789N19**

Registration date: **2018-06-05, 1397/03/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-05, 1397/03/15**

Update count: **0**

Registration date

2018-06-05, 1397/03/15

Registrant information

Name

Masoud Rasolabady

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 4654

Email address

rasolabady@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of surgery of endometriosis on fertility and it's complications in women with endometriosis	IR.MUK.REC.1396/375
Public title The effect of surgery of endometriosis on fertility in women with endometriosis Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: Women with endometrium more than 4 cm Age from 18 to 40 years Infertility Exclusion criteria: The presence of chronic internal diseases The definitive need for surgery Other causes of infertility Age From 18 years old to 40 years old Gender Female Phase 3 Groups that have been masked <i>No information</i> Sample size Target sample size: 64 Randomization (investigator's opinion) Randomized Randomization description Patients will be randomly selected based on quadruple blocks. Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features	Health conditions studied <u>1</u> Description of health condition studied Female infertility ICD-10 code N97 ICD-10 code description Female infertility Primary outcomes <u>1</u> Description Pregnancy Timepoint Three months and six months after the intervention Method of measurement Successful pregnancy with healthy fetus based on ultrasound Secondary outcomes <u>1</u> Description Pregnancy Complications Timepoint Three months and six months after the intervention Method of measurement Observing complications such as abortion Intervention groups
Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Kurdistan University of Medical Sciences Street address Pasdaran St. City Sanandaj Province Kurdistan Postal code 66177-13446 Approval date 2018-03-14, 1396/12/23 Ethics committee reference number	<u>1</u> Description Intervention group: Endometrioma surgery was performed for patients in the intervention group with an endometrium size of more than 4 cm. Category Treatment - Surgery <u>2</u> Description Control group: Endometrioma surgery was not performed for patients in the control group. Category Treatment - Surgery Recruitment centers <u>1</u> Recruitment center Name of recruitment center

Besat Hospital

Full name of responsible person

Maryam Ghorbanian

Street address

Keshavarz St.

City

Sanandaj

Province

Kurdistan

Postal code

66186-34683

Phone

+98 87 3328 5910

Email

Ghorbanian68@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research of Kurdistan University of Medical Sciences

Street address

Pasdaran St.

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4653

Email

Mozh.zarei@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Maryam Ghorbanian

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Pasdaran St.

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4673

Email

Ghorbanian68@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Fariba Seyedoshohadaie

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Pasdaran St.

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4674

Email

f.seyedoshohadaei@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Maryam Ghorbanian

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Pasdaran St.
City
Sanandaj
Province
Kurdistan
Postal code
66177-13446
Phone
+98 87 3366 4673
Email
Ghorbanian68@gmail.com

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data on the primary outcome (pregnancy) is for sharing.

When the data will become available and for how long

One year after the publication the data will be available.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Meta-analysis is allowed on the data of this study.

From where data/document is obtainable

Dr. Maryam Ghorbanian, Pasdaran St., Kurdistan
University of Medical Sciences, Sanandaj, Iran , Email:
Ghorbanian68@gmail.com

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

After one year of publishing the article and publishing the results, those who need the data of this study, could apply via email.

Comments