Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of anti-adhesion substances in reducing adhesions after laparoscopic endometriosis surgery

Protocol summary

Study aim

Determining the effect of anti-adhesion substances in reducing adhesions after laparoscopic endometriosis surgery

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. For randomization, the block randomization method will be used using: www.sealedenvelope.com.

Settings and conduct

This study will be done at Avicenna fertility center and Kamali hospital in karaj city. Patients with advanced endometriosis who underwent surgery during surgery after releasing the adhesion, the material is placed in the places where the adhesion have been opened (intervention group). No intervention is performed for the control group. And between 3 and 6 months after surgery, they undergo ultrasound and the amount of adhesion is determined by ultrasound and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients referred to Avicenna endometriosis clinic and Kamali hospital in Karaj who are diagnosed with severe endometriosis (stage 3 and 4) according to clinical and sonographic criteria; Women in the age group of 15 to 45 years; Women diagnosed with infertility; Women with chronic cyclic pelvic pain associated with menstruation.Exclusion criteria :Pregnant or lactating women, Having Laparoscopy contraindications (coagulopathy, cirrhosis, unclear anatomy, heart, lung disease)

Intervention groups

Intervention group: During laparoscopic surgery for endometriosis, after releasing the adhesions and shaving the intestine, the anti-adhesion material (interguard oxidized regenerated cellulose, Samyang biofarm company, Made in Hungary) is placed placed in the parts where the adhesion is opened. Control group: No intervention.

Main outcome variables

Abdominal and pelvic adhesion using ultrasound, 3-6 months after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221121056562N1**
Registration date: **2023-01-25, 1401/11/05**
Registration timing: **prospective**

Last update: **2023-01-25, 1401/11/05**
Update count: **0**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name
Shiva Mahmooudzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2237 1991
Email address
shiva.kani91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of anti-adhesion substances in reducing adhesions after laparoscopic endometriosis surgery

Public title

Investigating the effect of anti-adhesion substances in reducing adhesion after laparoscopic endometriosis surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women in the age group of 15 to 45 years Women diagnosed with infertility Women with chronic cyclic pelvic pain associated with menstruation Patients who are diagnosed with severe endometriosis (stage 3 and 4) according to clinical and ultrasound criteria.

Exclusion criteria:

Pregnancy Lactating lady Laparoscopy contraindications (coagulopathy - cirrhosis - unclear anatomy - heart - lung disease)

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 60 people, with 30 people in each group. We will use the block randomization method by using: www.sealedenvelope.com. The number of blocks considered is 4.

Blinding (investigator's opinion)

Double blinded

Blinding description

The statistician will be unaware of the intervention method. Participants are unaware of the type of intervention. Injections are performed by a surgeon as a result of the surgeon and assistant surgeon are aware of the type of intervention. The person who records the final result of the study is unaware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Alborz University of Medical Sciences

Street address

Ethics committee unit; Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street

City

Tehran

Province

Tehran

Postal code

3149779453

Approval date

2022-11-02, 1401/08/11

Ethics committee reference number

IR.ABZUMS.REC .1401. 199

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Abdominal adhesions

Timepoint

Three to six months after surgery

Method of measurement

Sonography , According to the scoring system Enzian

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: During laparoscopic surgery for endometriosis, after releasing the adhesions and shaving the intestine, the anti-adhesion material (interguard oxidized regenerated cellulose, 7.5-10 cm ,Samyang biofarm company, Made in Hungary) is placed placed in

the parts where the adhesion is opened. Its amount is determined based on the extent of adhesion during surgery

Category

Prevention

2

Description

Control group: During laparoscopic endometriosis surgery, no intervention is performed

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital

Full name of responsible person

Shiva Mahmoodzadeh

Street address

Kamali hospital; Kamali alley; Shohada square; Shahid Beheshti street

City

Karaj

Province

Alborz

Postal code

3145746486

Phone

+98 26 3240 2161

Email

kamali@abzumbs.ac.ir

2

Recruitment center

Name of recruitment center

Avicenna Fertility Center

Full name of responsible person

Shiva mahmoodzadeh

Street address

No. 97, Dr. Shariati St

City

Tehran

Province

Tehran

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1941913114

Phone

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Email

info@avicennaclinic.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Nourisepehr

Street address

Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street

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Karaj

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Alborz

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3198764653

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Email

Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Shiva Mahmooudzadeh

Position

Resident of Obsetetrics and gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kamali hospital; Kamali alley; Shohada square; Shahid Beheshti street

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Phone

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Email

shiva.kani91@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Shiva Mahmooudzadeh

Position
Resident of Obsetetrics and gynecology

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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