

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison the effect of ovarian suspension and hyaluronic acid gel in prevention of ovarian re-adhesion after laparoscopic surgery for stage 3&4 endometriosis. A Randomized, Double-blind Clinical trial

#### Protocol summary

##### Summary

This study aimed to Comparison the effect of ovarian suspension and hyaluronic acid gel in prevention of ovarian re-adhesion after laparoscopic surgery for stage 3&4 endometriosis. After confirming the inclusion criteria and obtain the written consent of the individual, randomly one of the ovaries of the group ovarian suspension and the other hyaluronic acid gel is assigned. For random allocation of ovaries in each one of random sampling and in order to hide the sealed envelopes and then use the results of an ultrasound can be used during laparoscopy. The patients in the laparoscopic surgery and after the release of adhesions, a fixed ovaries and ovarian abdomen is covered by the Endogel. The patients after surgery then will be assessed 3 month later. Sample size in study is 50 patients. The primary outcome is the occurrence of adhesions that this will be assessed by ultrasound. Secondary outcomes include the severity of adhesions, the degree and depth of ovarian inactivity is determined by ultrasound. Inclusion criteria, all patients 18 to 40 years old with chronic pelvic pain of endometriosis with grade 3 and 4, severe menstrual pain, suffering and in examinations and tests, ultrasound or MRI strong doubt has been created to endometriosis. Exclusion criteria include patients who have a tendency to review the plan or during laparoscopic bilateral ovarian adhesion is not observed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015081723666N1**  
Registration date: **2015-12-19, 1394/09/28**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-12-19, 1394/09/28

##### 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 Sciences

##### Expected recruitment start date

2015-12-01, 1394/09/10

##### Expected recruitment end date

2016-11-01, 1395/08/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of ovarian suspension and hyaluronic acid gel in prevention of ovarian re-adhesion after laparoscopic surgery for stage 3&4 endometriosis. A Randomized, Double-blind Clinical trial

##### Public title

The effect of ovariopexy and endogel in prevention of

endometriosis readhesion

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: 18 to 40 years old patients suspicious to stage 3 & 4 endometriosis, because of chronic pelvic pain, severe dysmenorrhea dyspareunia and infertility, positive physical examinations and related tumor markers, ultrasound or MRI, who are candidate for laparoscopic surgery and have signed a consent form.

Exclusion criteria: Patients who have not signed the consent form and have not shown bilateral ovarian adhesions at the time of laparoscopy, or have any contraindication for surgery and anesthesia.

### **Age**

From **18 years** old to **40 years** old

### **Gender**

Female

### **Phase**

3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **50**

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

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee Iran University of Medical Science

##### **Street address**

Iran . Tehran . Hemat Highway . Milad Tower

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2015-08-03, 1394/05/12

#### **Ethics committee reference number**

IR.IUMS.REC.1394

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Endometriosis

#### **ICD-10 code**

N 80.0

#### **ICD-10 code description**

Endometriosis of uterus

## **Primary outcomes**

### 1

#### **Description**

Ovarian adhesion

#### **Timepoint**

3 months after surgery

#### **Method of measurement**

To determine the adherence of patients a questionnaire developed by the researchers used ultrasound accreditation by the outcome of the results of ultrasound during laparoscopy is examined

## **Secondary outcomes**

### 1

#### **Description**

pain

#### **Timepoint**

3 month after operation

#### **Method of measurement**

Visual analogue scale

## **Intervention groups**

### 1

#### **Description**

Application of Hyaluronic Acid gel to to the adhesion site.

#### **Category**

Prevention

### 2

#### **Description**

Fixation of the ovary to abdominal wall

#### **Category**

Prevention

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Rasoul e Akram Hospital

##### **Full name of responsible person**

Abolfazal Mehdizadeh Kashi

##### **Street address**

Niayesh Av. Sattar khan St. Tehran, Iran

##### **City**

Tehran

## 2

### Recruitment center

**Name of recruitment center**

Pars General Hospital

**Full name of responsible person**

Dr. Shahla Chaichian

**Street address**

No11, Saeedi Alley, Fereshteh St

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Ali Javad Musavi

**Street address**

Research Deputy office of Iran University of Medical Sciences

**City**

Tehran

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Science

**Full name of responsible person**

Abolfazl Mehdizadeh

**Position**

MD. Professor of Obstetrics and Gynecology

**Other areas of specialty/work**

**Street address**

Rasoul Akram Hospital, Niayesh Av. Sattar khan St.  
Tehran, Iran

**City**

Tehran

**Postal code**

1449613131

**Phone**

+98 21 6650 9283

**Fax**

**Email**

amehdizadehkashi@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University, Tehran Medical Sciences Branch

**Full name of responsible person**

Dr. Shahla Chaichian

**Position**

Associate Professor Fellowship of Laparoscopic Gynecology

**Other areas of specialty/work**

**Street address**

No 11, Saeedi Alley, Fereshteh St.

**City**

Tehran

**Postal code**

**Phone**

+98 21 2264 8065

**Fax**

+98 88966052

**Email**

shchaichian@yahoo.com: shchaichian@gmail.com:  
shchaichian@iautmu.ac.ir: shchaichian@iautmu.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Science

**Full name of responsible person**

Abolfazal Mehdizadeh Kashi

**Position**

MD, Assistant professor of Obstetrics and Gynecology

**Other areas of specialty/work**

**Street address**

Niayesh Av, Sattar khan St, Tehran, Iran.

**City**

Tehran

**Postal code**

1449613131

**Phone**

+98 21 6650 9283

**Fax**

**Email**

amehdizadehkashi@yahoo.com

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*