

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effectiveness of Hysteroscopic Endometrial resection on the prevention of the endometrial polyps recurrence

Protocol summary

Study aim

The aim of this study was to investigate the effect of endometrial resection by hysteroscopy in preventing recurrence of endometrial polyps in patients with polyps at the age of 40 and over, referred to Rasoul-e-Akram Hospital in 1396

Design

The present study is a clinical trial study that will be carried out on 94 women with polyps at the age of 40 years after applying the exclusion and Inclusion criteria.

Settings and conduct

For this research, after receiving the ethical confirmation from the Ethics Committee of Iran University of Medical Sciences, patient with endometrial polyps referring to the Department of Obstetrics and Gynecology of Rasoul Akram Hospital and those patients who are not willing to become pregnant, candidates for hysteroscopic polypectomy . Selection is done completely randomly. They are divided into two groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Endometrial polyps; over 40 years of age; Satisfaction to participate in the study. Non-inclusion criteria: presence of high blood pressure or diabetes mellitus; tamoxifen consumption; presence of endometrial resection indication.

Intervention groups

Intervention: The first group include 47 patients who will receive the desired intervention, means endometrial resection. The second group won't undergo endometrial resection.

Main outcome variables

Intervention outcome: After a maximum of 3 months after surgery, patients are contacted in both groups and invited to visit and performing TVS ultrasound. The purpose of this ultrasound is to R/O permanent polyps. Then, at intervals of 6 to 12 months after surgery, the patients are contacted for evaluation early onset recurrence and invited to visit for performing TVS. If the radiologist needs another diagnostic method in relation

to the probability of recurrence, then this will be done by the SIS at the discretion of the patient. Outcome Measurement Tool: Transvaginal sonography and, if necessary, SIS. Main outcome Variable : Endometrial polyps recurrence that measured through transvaginal sonography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150909023949N7**

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

Registration timing: **retrospective**

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

Update count: **0**

Registration date

2018-01-28, 1396/11/08

Registrant information

Name

Mansoureh Vahdat

Name of organization / entity

Iran University of medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9283

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-10-08, 1396/07/16
Expected recruitment end date
2017-11-06, 1396/08/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Hysteroscopic Endometrial resection on the prevention of the endometrial polyps recurrence

Public title
Effectiveness of Hysteroscopic Endometrial resection on the prevention of endometrial polyps recurrence

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Endometrial polyps over 40 years of age Satisfaction to participate in the study
Exclusion criteria:
presence of Hypertension or diabetes Tamoxifen consumption dissatisfaction to participate in the study presence of endometrial resection indication

Age
From **40 years** old to **68 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization using random numbers table

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients, the person who evaluates the outcome of the study, and the person analyzing the data will not know the random allocation of the individuals to the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Iran University of Medical Sciences

Street address

Iran University Of Medical Sciences, next to Milad tower, Hemmat highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۲۹۶۱۴۵۳۵

Approval date

2017-10-07, 1396/07/15

Ethics committee reference number

IR.IUMS.REC 1396.30651

Health conditions studied

1

Description of health condition studied

Endometrial polyp

ICD-10 code

N84.0

ICD-10 code description

Polyp of corpus uteri

Primary outcomes

1

Description

recurrence of Endometrial polyp

Timepoint

6 months after histerscopy

Method of measurement

trans vaginal sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group after anesthesia, and placing the patient in the lithotomy position, hysteroscope will be introduced and uterine cavity will be observed. After cavity and ostium vision, polypectomy will be done if the polypomatose lesion is observed. Then endometrial resection will be done by resectoscope.

Category

Treatment - Surgery

2

Description

Control group: after anesthesia, and placing patient in the lithotomy position, hysteroscope will be introduced and uterine cavity will be observed. After cavity and ostium vision, polypectomy will be done if the polypomatose lesion is observed. Polypectomy will be done by scissor, grasper or resectoscope . In this group endometrial resection will not be done.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul E Akram Hospital

Full name of responsible person

Dr.Mania Kaveh

Street address

Endometriosis Research Center, Hazrat Rasool Akram Educational and Research Center, Niayesh Avenue, Sattarkhan Ave, Tehran

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maniakaveh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr Seeyd Kazem Malekouti

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Iran University Of Medical Sciences, next to Milad tower, Hemmat highway, Tehran

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k.malekouti@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, 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

Dr. Mania Kaveh

Position

Assistant of womens Laparoscopic Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Endometriosis Research Center, Hazrat Rasool Akram Educational and Research Center, Niayesh Avenue, Sattarkhan Ave, Tehran

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Mansoureh Vahdat

Position

assistant professor

Latest degree

Specialist

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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data except personal information

When the data will become available and for how long

After the article is published

To whom data/document is available

Obstetricians and gynecologists who are going to do more research

Under which criteria data/document could be used

further research

From where data/document is obtainable

Dr. Kaveh via email: maniakaveh@gmail.com

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

Request via email

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Rasoul Akram Hospital

Full name of responsible person

Dr. Mania Kaveh

Position

Fellowship of minimally invasive gynecologic surgery

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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