Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Compare of Cavaterm endometrial ablation Vs. hysteroscopic endometrial ablation in treatment of abnormal uterine beeding

Protocol summary

Study aim
Comparison of Cavaterm endometrial ablation Vs. hysteroscopic endometrial ablation in treatment of abnormal uterine beeding

Design
Randomized clinical trial with two 50 patients, parallel group, open lable , ranomized with Rand function of Excel software

Settings and conduct
this study was performed on women with abnormal uterine bleeding who were candidates for endometrial ablation in Akbarabadi and Hazrat Rasoul hospitals in Tehran to reduce bleeding. In this study, patients were randomly treated with endometrial ablation by one of two methods, hysteroscopy and cavaterm. Three, six and twelve months after the intervention follow up was performed to determine treatment response , including the percentage of amenorrhea, change in bleeding pattern and treatment satisfaction. Patients in this study are aware of the treatment used and blindness has not occurred.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Non nullipar women in the age range between 35-55; Abnormal uterine bleeding (AUB); Lack of proper response to medical treatment; Not trying to conceeve more; Unwillingness to hystrectomy; Exclusion criteria: Malignancy which confirmed in pathology; Submucosal myoma ; Uterine cavity distortion; Uterine size > 20 weeks;

Intervention groups
Endometrial ablation with Cavaterm thermal baloon
Endometrial ablation with hystroscopy

Main outcome variables
Amenorhea incidence, Severiry of menstraul bleeding, Satisfaction after the surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220210053986N1**
Registration date: **2022-03-06, 1400/12/15**
Registration timing: **retrospective**

Last update: **2022-03-06, 1400/12/15**
Update count: **0**

Registration date
2022-03-06, 1400/12/15

Registrant information
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Sepideh Azizi
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-09-20, 1399/06/30

Actual recruitment start date
2019-12-29, 1398/10/08

Actual recruitment end date
2020-10-21, 1399/07/30

Trial completion date
2021-10-22, 1400/07/30

Scientific title
Compare of Cavaterm endometrial ablation Vs. hysteroscopic endometrial ablation in treatment of abnormal uterine beeding

Public title
Comparison of Cavaterm endometrial ablation Vs. hysteroscopic endometrial ablation in treatment of abnormal uterine beeding
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Non nullipar women in the age range between 35-55 Abnormal uterine bleeding (AUB) Lack of proper response to medical treatment Not trying to conceeve more Unwillingness to hystrectomy
Exclusion criteria:
Malignancy which confirmed in pathology (Curretage or piple biopsy sample) Grade 0 & 1 submucosal myoma in sonography Uterine cavity distortion Uterine size > 20 weeks
Age
From **35 years** old to **55 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into two groups by simple randomization using Excel software and using the RAND function. A column of 100 numbers is created in Excel software containing 50 codes A (cavater group) and 50 codes B (hysteroscopic group). The parallel column contains one hundred random numbers will be generated by the RAND function. After arranging the randomized column while maintaining the connection to the first column, a random sequence is prepared and patients are divided into two groups, respectively.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of School of Medicine, IUMS
Street address
Hemmat exp.way
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۲۵
Approval date
2019-12-29, 1398/10/08
Ethics committee reference number
IR.IUMS.FMD.REC.1398.437

Health conditions studied

1

Description of health condition studied
Abnormla Uterine Bleeding
ICD-10 code
N93
ICD-10 code description
Other abnormal uterine and vaginal bleeding

Primary outcomes

1

Description
Amenorhea incidence
Timepoint
Months 3,6 and 12 after surgery
Method of measurement
Clinical history

Secondary outcomes

1

Description
Need to hystrectomy
Timepoint
Months 3, 6 and 12 after surgery
Method of measurement
Clinical history

2

Description
Menstraul bleeding severity
Timepoint
Months 3,6 and 12 after surgery
Method of measurement
Days of menstraul bleeding and number of used menstrual pads

3

Description
Satisfaction after surgery
Timepoint
Months 3,6 and 12 after surgery

Method of measurement
Likert scale

Intervention groups

1

Description
Intervention group: Endometrial ablation by the Cavtherm thermal balloon method: The Cavaterm method is based on the rotation of hot water with a temperature of about 80 ° C at a constant pressure between 240-230 mm Hg in a silicon balloon for 10 minutes. The Cavaterm system consists of a disposable catheter with an adjustable silicone balloon and a central unit. 10 minute treatment is a combination of heat, circulation and also water pressure to coagulate the endometrium and its underlying myometrial layer in depth of 5 to 9 mm.
Category
Treatment - Surgery

2

Description
Control group: Endometrial ablation by hysteroscopic method: First in the operating room, after filling and emptying and emptying the bladder, uterus, adnexa, is determined by double-handed examination of the touch and position of the uterus. After venting the normal saline and white balance dilating media system with a 4.5 mm diagnostic hysteroscope, the uterine cavity was examined in all directions. In the absence of a problem, the lower valve of the vagina is inserted and the anterior edge of the cervix is closed with a tenaculum, and uterine curettage is performed in all directions. After re-ventilation and performing white balance, it enters the endometrial cavity and the endometrial cavity is coagulated with a hysteroscope with a power of 50-150 watts, depending on the size of the electrode, depending on the size of the electrode and coagulation. The lateral and eventually the posterior wall is destroyed. In this method, during the destruction, it is activated only when the electrode moves towards the surgeon, at the same time, it tries to avoid the destruction of the cervical mucosa.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi hospital
Full name of responsible person
Mahdis Mohammadian
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Sponsors / Funding sources

1

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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
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Sepideh Azizi
Position
Resident of gynecology
Latest degree
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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