Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Operative hysteroscopy in patients with active uterine bleeding with and without uterine evacuation prior to the procedure:comaring the results

Protocol summary

Study aim

Operative hysteroscopy in patients with active uterine bleeding with and without uterine evacuation prior to the procedure:comaring the results

Design

This clinical trial study will be performed on 114 patients referring to the Alzahra hospital oncology clinic with abnormal uterine bleeding and in one ultrasonography, one of the diagnosis of polyp, submucosal mialis, or endometrial thickening was presented. Or they did not have an outpatient biopsy, or they were inadequate and were candidates for hysteroscopy and D & C.To divide patients into two intervention and control groups the Rand list will be used.Then the grouping numbers will be placed in the envelope These envelopes will be prepared by the person who is not involved in their preparation and issue.This person will not be responsible for any patient selection process, intervention and data analysis.

Settings and conduct

This clinical trial study will be performed on 114 patients referring to the Alzahra hospital oncology clinic with abnormal uterine bleeding.Patients will be divided into two groups of intervention and control groups.

Participants/Inclusion and exclusion criteria

Women with active hemorrhage, who are candidates for hysteroscopy, will be included in the study and will not be considered if they have coagulation disorders.

Intervention groups

In the intervention group: First, with the ring of forceps and curettes, the clots and contents of the cavity of the uterus are drained then the resectoscope enters the uterine cavity to examine the cavity and remove visible lesions and if not seen biopsy Lesion is removed under direct vision and then the curettage is done.In the control group: The resectoscope enters the uterine cavity directly and removes visible lesions and after removing the resectoscope curettage is done.

Main outcome variables

Interaoperative bleeding; Hematocrit loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005283N13**
Registration date: **2018-11-16, 1397/08/25**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-16, 1397/08/25**
Update count: **0**

Registration date

2018-11-16, 1397/08/25

Registrant information

Name

Manizheh Sayyah Melli

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 3741

Email address

sayyahmellim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-11, 1397/08/20

Expected recruitment end date

2020-09-10, 1399/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Operative hysteroscopy in patients with active uterine bleeding with and without uterine evacuation prior to the procedure:comaring the results

Public title
Operative hysteroscopy in patients with active uterine bleeding with and without uterine evacuation prior to the procedure:comaring the results
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with abnormal uterine bleeding Diagnosis of polyps, submucosal miosis, or endometrial thickening is given in ultrasound. Satisfaction to participate in the study
Exclusion criteria:
Dissatisfaction to participate in the study Pregnant patients Patients with coagulation disorders
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **114**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random method will be used. So patients will be referred to the intervention and control group, 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
Ethics Committee Of Tabriz University Of Medical Sciences
Street address
Golgasht Street ,Tabriz University Of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166615953
Approval date
2018-10-22, 1397/07/30
Ethics committee reference number
IR.TBZMED.REC.1397.612

Health conditions studied

1

Description of health condition studied
Abnormal uterine and vaginal bleeding, unspecified
ICD-10 code
N93.9
ICD-10 code description
Abnormal uterine and vaginal bleeding, unspecified

Primary outcomes

1

Description
Interaoperative bleeding
Timepoint
At the end of surgery
Method of measurement
Visual scale

2

Description
duration of surgery
Timepoint
From the beginning to the end of surgery
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Hematocrit loss
Timepoint
6 hour after surgery
Method of measurement
blood test

Intervention groups

1

Description
In the intervention group: First, with the ring of forceps and curettes, the clots and contents of the cavity of the uterus are drained then the resectoscope enters the uterine cavity to examine the cavity and remove visible lesions and if not seen biopsy Lesion is removed under direct vision and then the curettage is done.

Category
Treatment - Surgery

2

Description
In the control group: The resectoscope enters the uterine cavity directly and removes visible lesions and after removing the resectoscope curettage is done.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Dr.Manizheh Sayyah-Melli
Street address
Alzahra Hospital, South Artesh Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3553 9161
Email
lahroudin@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research,Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Alireza Rashidi
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3556 9543
Fax
Email
lahroudin@gmail.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,Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Manizheh Sayyah-Melli
Position
prof. of Ob & Gyn
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Golgasht Street, Tabriz University Of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3556 9543
Email
lahroudin@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Manizheh Sayyah-Melli
Position
prof. of Ob & Gyn
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Golgasht Street, Tabriz University Of Medical Sciences
City
Tabriz
Province
East Azarbaijan

Postal code
5138665793
Phone
+98 41 3556 9543
Email
lahroudin@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Manizheh Sayyah-Melli
Position
prof. of Ob & Gyn
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Golgasht Street ,Tabriz University Of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3553 9161
Email
lahroudin@gmail.com

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