

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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)

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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

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Tabriz

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5138665793

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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

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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

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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