

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison the accuracy and complication of D&C and endometrial biopsy in patient with abnormal uterine bleeding

Protocol summary

Summary

Objectives Endometrial biopsy has less use as first-line diagnostic method for abnormal uterine bleeding. In this study, the results of endometrial biopsy and diagnostic curettage will be compared for endometrial histopathology, adequacy obtained endometrial tissue by biopsy, complications and failure rates of these methods. First aim is evaluation of Pipelle techniques validity and accuracy for determining of endometrial histopathology in patients who present with abnormal uterine bleeding, especially for rolling out of endometrial cancer and second aim is evaluation the adequacy of obtained sample for histopathological examination, accompanying complications and the failure rate of pipelle method and comparison with diagnostic curettage technique. In this study, the failure rate is presence of any type of pathology in diagnostic curettage specimens that have not been diagnosed with pipelle. Design, Setting and conduct This is an analytical study which perform on women with abnormal uterine bleeding by sequential sampling techniques for women who will enrolled in study. All patients underwent clinical and laboratory examinations. Participants, inclusion and exclusion criteria All women older than 35 years with abnormal uterine bleeding will enroll after informed consent. All women with pregnancy; hormonal disorders including thyroid, hepatic and renal diseases, lupus, diabetes; endometrial thickness less than 4 millimeter; lower genital tract infection will exclude from study. Intervention Diagnostic intervention is endometrial biopsy which does by pipelle and diagnostic standard reference is endometrial sampling by curettage. Both techniques are performed in the operating room and at the same time. First pipelle enter to uterine cavity without cervical dilatation, then rotate and retract (pull back) for endometrial sampling. These samples are labeled "A". Then standard diagnostic curettage will do and samples are labeled "B". Both samples are sent for pathology that is unaware sampling method. These

samples will evaluate histopathologically. Main outcome Histopathology reports for sample by pipelle and diagnostic curettage are compared and diagnostic curettage report used as the gold standard.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081111504N4**

Registration date: **2013-10-29, 1392/08/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-29, 1392/08/07

Registrant information

Name

Sanam Moradan

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 1446 0066

Email address

smoradan@sem.ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Semnan University of Medical Sciences Address: Vice chancellor for research, Semnan University of Medical Sciences, Central Department of Semnan University of Medical Science, Basidj Bulvard, Semnan, I.R.Iran, Tel: 00982314441420

Expected recruitment start date

2013-10-07, 1392/07/15
Expected recruitment end date
 2014-03-06, 1392/12/15
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparison the accuracy and complication of D&C and endometrial biopsy in patient with abnormal uterine bleeding

Public title
 accuracy and complication of D&C and endometrial biopsy in patient with abnormal uterine bleeding

Purpose
 Diagnostic

Inclusion/Exclusion criteria
 Inclusion criteria: Women older 35 years who have abnormal uterine bleeding. Exclusion criteria: Pregnancy; hormonal disorders including thyroid, hepatic and renal diseases, lupus, diabetes; endometrial thickness less than 4 millimeter; lower genital tract infection.

Age
 No age limit

Gender
 Female

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **110**

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Semnan University of Medical Sicense

Street address

Central Department, Semnan University of Medical

Sicense, Basidj Bulvard
City
 Semnan
Postal code
Approval date
 2013-08-11, 1392/05/20
Ethics committee reference number
 28/20/7041

Health conditions studied

1

Description of health condition studied

Abnormal uterine bleeding

ICD-10 code

N93.9

ICD-10 code description

Abnormal uterine and vaginal bleeding, unspecified

Primary outcomes

1

Description

Accuracy of endometrial biopsy

Timepoint

After biopsy

Method of measurement

Comparison with diagnostic curettage

Secondary outcomes

empty

Intervention groups

1

Description

Diagnostic intervention is endometrial biopsy by pipelle and standard diagnostic reference is sampling by endometrial curettage. Both techniques are performed in the operating room and at the same time. First pipelle enter to uterine cavity without cervical dilatation and then rotate and retracted to get endometrial samples. These samples are labeled A. Then, standard diagnostic curettage will perform and samples are labeled B. Both samples are sent to a pathologist who is unaware from sample collection methods. The samples are evaluated and the results will compare. Diagnostic curettage report to be used as the gold standard.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Momenin Hospital
Full name of responsible person
Masomeh Mahboob
Street address
Amir Al Momenin Hospital, Imam Hussein Square
City
Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Semnan University of Medical Science
Full name of responsible person
Raheb Ghorbani Ph.D
Street address
Central Department of Semnan University of Medical Science, Basidj Bulvar
City
Semnan

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 of Semnan University of Medical Science

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
Semnan University of Medical Science
Full name of responsible person
Masomeh Mahboob
Position
Gynecology Resident
Other areas of specialty/work
Street address
Amir Al Momenin Hospital, Imam Hussein square
City
Semnan
Postal code
Phone
+98 23 1446 0077
Fax
Email

mehrdadzahmatkesh@sem-ums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Science
Full name of responsible person
Dr. Sanam Moradan
Position
Gynecologist
Other areas of specialty/work
Street address
Amir Al Momenin Hospital, Imam Hussein Square
City
Semnan
Postal code
Phone
+98 23 1446 0077
Fax
Email
smoradan@sem-ums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Science
Full name of responsible person
Mehrdad Zahmatkesh
Position
Research Expert
Other areas of specialty/work
Street address
Kowsar Hospital, Basidj Bulvar
City
Semnan
Postal code
Phone
+98 23 1443 7846
Fax
Email
mehrdadzahmatkesh@sem-ums.ac.ir
Web page address

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

