Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of diagnostic accuracy and side effects of endometrial biopsy curette, a product of Slamtyar Hakim Engineering Company

Protocol summary

Study aim

Determining and comparing the diagnostic accuracy of endometrial sampling with endometrial biopsy catheter produced by Health Engineering Company yar Hakim and dilatation and curettage

Design

In this study, 60 patients in the age range of 18-75 years who refer to endometrial tissue sampling for various reasons will be selected based on continuous sampling method and after obtaining informed consent will be examined. Due to the fact that patients are first biopsied from the endometrium by a court biopsy and then need general anesthesia, dilatation and curettage, in fact, these patients are selected as a control group to examine the endometrium with a curette, there is no need to match the age, cause of bleeding and delivery rank. These patients will be included in the study non-randomly after obtaining consent.

Settings and conduct

For sampling with a pipette, by suction of the syringe and pulling the end of the catheter tube, which has side holes, the excised tissue is inserted into the catheter. Then D&C is performed with cervical dilatation. Both samples obtained with a pipette and D&C are examined by a pathologist as a single blind.

Participants/Inclusion and exclusion criteria

The patient will be examined in the age range of 18-75 years after obtaining informed consent. Women with a history of endometrial cancer, atypical endometrial hyperplasia, a positive pregnancy test result, or unwillingness to participate are excluded from the study.

Intervention groups

Control group: Including 60 patients, dilatation and curettage operation will be performed for endometrial biopsy. Intervention group: Including 60 patients, endometrial biopsy catheter will be used for endometrial sampling, a product of Salamat yar Hakim Engineering Company.

Main outcome variables

Pathological outcome, patients' pain intensity, complications after biopsy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151120025139N2**
Registration date: **2022-01-23, 1400/11/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-23, 1400/11/03**
Update count: **0**

Registration date

2022-01-23, 1400/11/03

Registrant information

Name

fariba behnamfar

Name of organization / entity

medeical school of isfahan

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 5555

Email address

behnamfar_fa@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of diagnostic accuracy and side effects of endometrial biopsy curette, a product of Slamtyar Hakim Engineering Company

Public title

Evaluation of diagnostic accuracy and side effects of endometrial biopsy curette

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 75-18 Willingness to participate in the study

Exclusion criteria:

History of endometrial cancer History of atypical endometrial hyperplasia Positive pregnancy test result Reluctance to participate

Age

From **18 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Both samples obtained by piping and D&C will be examined as a blind by a pathologist skilled in the field. A sample with a patient-specific code will be sent to the pathologist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Third Floor, Salamat Town, Sepehr St, Shahid Aghababaei Highway,

City

Isfahan

Province

Isfehan

Postal code

8198314271

Approval date

2021-05-29, 1400/03/08

Ethics committee reference number

IR.MUI.MED.REC.1400.159

Health conditions studied

1

Description of health condition studied

Uterine endometrial biopsy

ICD-10 code

C55

ICD-10 code description

Malignant neoplasm of uterus, part unspecified

Primary outcomes

1

Description

Pathological outcome

Timepoint

10 days after biopsy

Method of measurement

Pathological evaluation

2

Description

Patients' pain intensity

Timepoint

Immediately after sampling

Method of measurement

Observation and questioning of the patient

3

Description

Complications after biopsy

Timepoint

After sampling

Method of measurement

Observe symptoms in the patient

Secondary outcomes

empty

Intervention groups

1

Description

Control group:Including 60 patients, dilatation and curettage operation will be performed for endometrial biopsy

Category

Diagnosis

2

Description

Intervention group:Including 60 patients, endometrial biopsy catheter will be used for endometrial sampling, a product of Salamat yar Hakim Engineering Company

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Shahid Beheshti Hospital

Full name of responsible person

Fatemeh Maghool

Street address

Shahid Beheshti Isfahan, Obstetrics and Gynecology Hospital, Ostad Motahhari St., Metal Bridge

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fmaghool@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Salamat yar Hakim Engineering Company

Full name of responsible person

Sayyed Emran Emami

Street address

No. 125, A01و Abu Reihan Building, University of Technology, Khomeini Shahr, Isfahan Province

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8415682020

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+98 31 3266 7542

Email

sayyedemranemami@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Salamat yar Hakim Engineering Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Poursina Hakim Research center

Full name of responsible person

Fatemeh Maghool

Position

Research Director

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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