

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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**  
Isfahan

**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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**Province**

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**Phone**

+98 31 3236 7001

**Email**

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, A01, Abu Reihan Building, University of Technology, Khomeini Shahr, Isfahan Province

**City**

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**Province**

Isfahan

**Postal code**

8415682020

**Phone**

+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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third floor, Salat Town, Shahid Aghababaei Highway

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**Person responsible for scientific inquiries**

**Contact**

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Poursina Hakim Research center

**Full name of responsible person**

Fatemeh Maghool

**Position**

Research Director

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## Person responsible for updating data

### 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  
**Street address**  
third floor, Salat Town, Shahid Aghababaei Highway  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**

## 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