

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of Vaginal Estrogen and Evening-primrose Tablets on Transformation Zone Visibility in Unsatisfactory Colposcopy

Protocol summary

Study aim

Determining the effect of vaginal estrogen and evening primrose pill in improving the observation of transformation zone in unsatisfactory colposcopy

Design

A parallel-group, single-blind, randomized, phase 3 clinical trial on 134 patients.

Settings and conduct

This study will be conducted in Arash Hospital. Patients with unsatisfactory colposcopy are divided into two groups. In the first group: daily conjugated estrogen vaginal cream daily for 3 consecutive weeks vaginally and in The second group: the use of evening primrose tablets in a dose of 1000 mg for 3 consecutive weeks is administered vaginally, after 4 weeks colposcopy is performed again.

Participants/Inclusion and exclusion criteria

Exclusion criteria: Cervical structural anomalies such as history of cervical insufficiency, Müllerian anomaly and history of conization Having contraindications or sensitivity to evening primrose or estradiol Cancer in the patient or a history of breast or ovarian cancer in the family History of smoking Active vaginal bleeding or pregnancy Post-menopausal women with an inflammatory pap smear or persistent vaginal discharge Taking aspirin or Flavix History of cardiovascular diseases and thromboembolism, sexually transmitted diseases, digestive diseases and neurological diseases, hypertension and coagulopathy, liver disease. Inclusion criteria: Women who are candidates for colposcopy and have an unsatisfactory colposcopy

Intervention groups

Intervention groups1: Daily conjugated estrogen vaginal cream (one applicator) vaginally for 3 consecutive weeks Intervention group2: Taking evening primrose tablets (manufactured by Iran's Barij Essential Oil Company) in a dose of 1000 mg vaginally for 3 consecutive weeks.

Main outcome variables

Satisfactoriness of colposcopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140820018866N10**

Registration date: **2023-01-05, 1401/10/15**

Registration timing: **prospective**

Last update: **2023-01-05, 1401/10/15**

Update count: **0**

Registration date

2023-01-05, 1401/10/15

Registrant information

Name

Afsaneh Tehranian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 3283

Email address

afsanehtehranian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Vaginal Estrogen and Evening-primrose Tablets on Transformation Zone Visibility in Unsatisfactory Colposcopy

Public title

Comparison of the effects of vaginal estradiol and evening primrose pills in improving the visualization of the cervix during colposcopy

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Women who are candidates for colposcopy and have an unsatisfactory colposcopy

Exclusion criteria:

Cervical structural anomalies such as history of cervical insufficiency, Müllerian anomaly and history of conization
Having contraindications or sensitivity to evening primrose or estradiol
Cancer in the patient or a history of breast or ovarian cancer in the family
History of smoking
Active vaginal bleeding or pregnancy
Post-menopausal women with an inflammatory pap smear or persistent vaginal discharge
Taking aspirin or Flax
History of cardiovascular diseases and thromboembolism, sexually transmitted diseases, digestive diseases and neurological diseases, hypertension and coagulopathy, liver disease
Thyroid dysfunction and thyroid medication use
Blood disorders

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **134**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process will be done using the website www.sealedenvelope.com and in block form. The number of blocks will be 6.

Blinding (investigator's opinion)

Single blinded

Blinding description

Concealment Type: Sealed Envelope
How to conceal: The random allocation list of patients will only be at the disposal of the plan's epidemiologist. In order to hide the random allocation process, a number of 134 sealed envelopes are prepared and a random 10-digit code is written on each envelope, which is the identification number of the relevant intervention, and only the methodologist of the project will be aware of the relevant code. All the envelopes are placed in a box in order based on the random allocation list and given to the person responsible for sampling. When the doctor

declares the eligibility of a patient, the sampler will provide the envelope design to the doctor. The desired treatment is selected based on the type of treatment mentioned in the envelope.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Science

Street address

Tehran University of Medical Science, Qods Street, Keshavarz Boulevard, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1507

Health conditions studied**1****Description of health condition studied**

Cesarean

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes**1****Description**

Satisfactoriness of colposcopy

Timepoint

4 weeks after the start of drug administration

Method of measurement

colposcopy

Secondary outcomes

1

Description

Side effects such as stomach pain, breast pain, bloating, headache, itching, nausea and vomiting, diarrhea, chest or leg pain, impaired vision or speech, skin sensitivity, abnormal vaginal bleeding, vaginal itching and irritation.

Timepoint

4 weeks after the start of drug administration

Method of measurement

Ask the patient

Intervention groups

1

Description

Intervention group: Daily conjugated estrogen vaginal cream (one applicator) vaginally for 3 consecutive weeks

Category

Treatment - Drugs

2

Description

Intervention group: Taking evening primrose tablets (manufactured by Iran's Barij Essential Oil Company) in a dose of 1000 mg vaginally for 3 consecutive weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash women's hospital

Full name of responsible person

Dr Afsaneh Tehranian

Street address

No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

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afsanehtehranian@yahoo.com

Web page address

<http://arash.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masood Younesian

Street address

Tehran University of Medical Sciences , Qhods st., Keshavarz Blvd.

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Afsaneh Tehranian

Position

Specialist of Obstetrics and gynaecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Dr. Afsaneh Tehranian

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Web page address**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