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

Satisfactoryness 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 Flavix 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
Satisfactoryness 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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1653915981
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Email
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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Postal code
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Phone
+98 21 8163 3698
Email
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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Arash hospital, Tehranpars, Resalat highway
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Person responsible for updating data

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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