Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of vaginal tablets produced at the Faculty of Pharmacy and Vagifem on vaginal dryness in patients with atrophic vaginitis.

Protocol summary

Summary

The aim of this randomized, double-blind clinical trial is comparing marketed drug vagifem and formulation which has been made in the Faculty of Pharmacy. In this study, 42 patients with atrophic vaginitis that meet the criteria for inclusion and exclusion are randomly assigned to one of the control or Intervention groups. Patients in the intervention group will receive new formulated 17 beta-estradiol vaginal tablets and in the control group will receive vagifem formulation in the same dose. The treatment protocol during 12 weeks, consist of daily single dose for two weeks, and followed by two tablets per week. Dysparenuia, vaginal dryness, discharge, irritation will be measured and compared in both groups. People with cervicitis, cervical dysplasia, Bacterial Vaginitis, visible cervical lesions and patients treated with oral estrogen are excluded. Outcomes of this study include the tablet side effects such as headache, nausea, abdominal pain and vaginal bleeding and cramping.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309298022N2**
Registration date: **2013-12-04, 1392/09/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-12-04, 1392/09/13

Registrant information

Name

Katayoun Derakhshandeh

Name of organization / entity

Hamadan University of Medical Sciences, Pharmacy school

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-11-06, 1392/08/15

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of vaginal tablets produced at the Faculty of Pharmacy and Vagifem on vaginal dryness in patients with atrophic vaginitis.

Public title

manufacturing Of estradiol vaginal tablets.

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Female; having atrophic vaginitis; approved by gynecologist exclusion sriteria: cervicitis; cervical dysplasia; Bacterial Vaginitis; visible cervical lesions; patients treated with oral estrogen.

Age

From **40 years** old to **90 years** old

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kermanshah University of Medical Sciences
Street address
Kermanshah University of Medical Sciences, Central Building, shahid Beheshti Blvd. Kermanshah
City
Kermanshah
Postal code
Approval date
2013-07-08, 1392/04/17
Ethics committee reference number
14414

Health conditions studied

1

Description of health condition studied
Atrophic vaginitis
ICD-10 code
N95.2
ICD-10 code description
Senile (atrophic) vaginitis

Primary outcomes

1

Description
Dysparenuia
Timepoint
Before and three months after intervention
Method of measurement
Satisfaction questionnaire based on VAS

2

Description
Vaginal discharge
Timepoint
Before and three months after intervention
Method of measurement
Satisfaction questionnaire based on VAS

3

Description
Vaginal dryness
Timepoint
Before and three months after intervention
Method of measurement
Satisfaction questionnaire based on VAS

4

Description
Vaginal irritation
Timepoint
Before and three months after intervention
Method of measurement
Satisfaction questionnaire based on VAS

Secondary outcomes

1

Description
Headaches
Timepoint
Before and three months after intervention
Method of measurement
Satisfaction on VAS

2

Description
Nausea
Timepoint
before and three months after intervention.
Method of measurement
Satisfaction on VAS

3

Description
vaginal bleeding
Timepoint
before and three months after intervention
Method of measurement
Satisfaction on VAS

Intervention groups

1

Description
Control group: vagifem vaginal tablets (25 micrograms 17 beta-estradiol) for 12 weeks, The first two weeks, one tablet a day, two pills per week for ten weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Formulated 17 beta-estradiol vaginal tablets (25 micrograms) in the Faculty of Pharmacy, Kermanshah, for 12 weeks. The first two weeks, one tablet a day, two pills per week for ten weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. maryam zangene
Street address
Imam Reza Hospital, Zakaria Razi Blvd. Kermanshah
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice – Chancellery of Research & Technology Affairs, Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Building 2 Mant of Vice – Chancellery of Research & Technology Affairs, Shahid Beheshti Blvd.
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice – Chancellery of Research & Technology Affairs, Kermanshah University of Medical Sciences
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
Faculty of Pharmacy, Kermanshah University of Medical Sciences
Full name of responsible person
Dr.Katayoun Derakhshandeh
Position
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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

Data Dictionary

empty