Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Comparison of the effects of hyaluronic acid and conjugated estrogen vaginal cream (Prmarin) on vaginal atrophy in menopausal women referred to selected clinics affiliated to Shiraz university of medical sciences, 1391

Protocol summary

Summary

(1)Objectives The aim of this study was to comparison of the effects of hyaluronic acid and conjugated estrogen vaginal cream (Prmarin) on vaginal atrophy. (2) Design Random, not blinded, single- center, phase 3-2 clinical trial (3)Setting and conduct They are divided into two groups receiving vaginal cream hyaluronic acid (n=28) and conjugated estrogen vaginal cream (Prmarin), (n=28) for 8 weeks. (4)Participants including major eligibility criteria Inclusion criteria: Married and menopausal women with symptoms, No smoking, No use of Anticoagulants drugs such as Heparin, Dryness and moderate to severe pain in the region of the vagina during intercourse, Not using vaginal drugs hormonal and non- hormonal 30 days before treatment; Absence of known or suspected history of hormone-dependent diseases such as (Breast cancer , Unexplained vaginal bleeding and…) Exclusion criteria: Vaginal infection requiring treatment, Allergy (Rash, Erythema, Inflammation ...) to the drug or its ingredients, Not wanting to continue working Sample population: 56 (5)Interventions: Conjugated estrogen vaginal cream drug (Prmarin) to a group of patients, eight weeks, two weeks remaining in the first row and the same dose twice a week for six weeks. Hyaluronic acid vaginal cream medication to a group of patient, eight weeks (6)The main outcome variables: Vaginal maturation, measured before and after interventions by calculating the percentage of cells in Pap smear. PH vaginal tape measure before and after intervention by using PH meter strips.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022712644N1**
Registration date: **2013-09-15, 1392/06/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-15, 1392/06/24

Registrant information

Name

Tayebe Davari Dehpiri

Name of organization / entity

Shiraz university of medical siences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Shiraz University of Medical Sciences

Expected recruitment start date

2013-08-19, 1392/05/28

Expected recruitment end date

2015-02-17, 1393/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Comparison of the effects of hyaluronic acid and conjugated estrogen vaginal cream (Prmarin) on vaginal atrophy in menopausal women referred to selected clinics affiliated to Shiraz university of medical sciences, 1391

Public title
Effect of hyaluronic acid on vaginal atrophy in postmenopausal women
Purpose
Treatment
Inclusion/Exclusion criteria
Major inclusion criteria: Married women past menopause who have symptoms؛Non-Smoking؛ The use of drugs such as Heparin anticoagulants؛ Vaginal dryness and moderate to severe pain in the area during intercourse. (measured by visual criteria)؛ Do not use vaginal medications, hormonal and non-hormonal treatment for 30 days before؛ No history of known or suspected hormone-dependent diseases such as (breast cancer, cases of unexplained vaginal bleeding, acute Phlebitis or Thromboembolic disorders associated with estrogen and ...) Major exclusion criteria: Need to cure vaginal infection in primary screening for Pap smear؛ Sensitivity (rash, erythema, inflammation, ...) to the drug or its ingredients؛ Lack of desire to continue working
Age
From **45 years** old to **65 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand Street
City
Shiraz
Postal code
7193613119
Approval date
2013-08-19, 1392/05/28
Ethics committee reference number
92-6681

Health conditions studied

1

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

Primary outcomes

1

Description
Maturity of vagina.
Timepoint
Before and after eight weeks (end of intervention)
Method of measurement
Calculate the percentage of cells in pap smear

2

Description
Vaginal PH
Timepoint
Before and after eight weeks (end of intervention)
Method of measurement
By PH meter strips

Secondary outcomes

1

Description
Vaginal dryness
Timepoint
Before and after the intervention
Method of measurement
VAS

2

Description
Vaginal itching
Timepoint
Before and after the intervention
Method of measurement
VAS

3

Description
Urine incontinence
Timepoint
Before and after the intervention
Method of measurement
VAS

4

Description
Dyspareunia
Timepoint
Before and after the intervention
Method of measurement
VAS

Intervention groups

1

Description
Conjugated estrogen vaginal cream drug (Prmaryn) to a group of patients / eight weeks / two weeks remaining in the first row and the same dose twice a week for six weeks.
Category
Treatment - Drugs

2

Description
Hyaluronic acid vaginal cream medication to a group of patient / eight weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical Hospital Hazrat Zainab (sa)
Full name of responsible person
Tayebe Davari Dehpiri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Shiraz University of Medical Sciences
Full name of responsible person
Dr.Gholamreza Hatam
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Vice chancellor for research Shiraz University of Medical Sciences, The Seventh floor, Central Building of Shiraz University of Medical Sciences, Zand Street
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Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research Shiraz 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
College of Nursing and Midwifery, Shiraz
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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