

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 sciences

Country

Iran (Islamic Republic of)

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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

Street address

Medical Hospital Hazrat Zainab (sa), Defa'e Moqadas Square

City

Shiraz

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

Full name of responsible person

Tayebe Davari Dehpiri

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Master of Midwifery

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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