

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of vitamin D and E vaginal suppository on vaginal atrophy in women with breast cancer who taking tamoxifen

Protocol summary

Summary

The aim of this study is to compare the effectiveness of vitamin D and E vaginal suppository on vaginal atrophy in women with breast cancer who taking tamoxifen. Material and Method: this randomized, double blind controlled trial will carry out at in Motahari breast clinic, Shiraz. A total of 150 women with breast cancer with symptoms of vaginal atrophy are randomly assigned to three groups to receive vaginal suppositories. 50 patients will take placebo vaginal suppositories containing 2 gr base material, (Suppocire AS2), 50 patients will take vitamin D vaginal suppositories (1000 IU Vitamin D equivalent to 0/025 mg of vitamin D in addition to the base material), and 50 patients will take vitamin E vaginal suppositories (1 mg vitamin E in addition to the base material). Symptoms of vaginal atrophy are confirmed by assessing vaginal PH (by PH indicator strip, construction by Sigma-Aldrich Germany with accuracy of 0.5), measuring vaginal maturation index (VMI), and subjective symptoms of vaginal atrophy according to self-assessment urogenital atrophy questionnaire (UAQ). If vaginal atrophy is approved (PH Score of 5 or greater than 5, VMI score 52 or less and at least one of the items of the UAQ), 14 vaginal suppositories will be given to any person. After two weeks, the other 14 vaginal suppositories will be given and subjective symptoms of vaginal atrophy will be assessed by UAQ and the vaginal PH is measured. After two weeks, besides the delivery of the remaining 28 suppositories, subjective symptoms of vaginal atrophy is evaluated and vaginal PH is measured. Four weeks later, in addition to evaluating subjective symptoms of vaginal atrophy, vaginal PH level and the vaginal maturation index is also checked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100229683N2**

Registration date: **2016-10-31, 1395/08/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-31, 1395/08/10

Registrant information

Name

zahra keshavarzi

Name of organization / entity

School of Nursing and Midwifery, 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

2016-10-05, 1395/07/14

Expected recruitment end date

2017-02-02, 1395/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D and E vaginal suppository on

vaginal atrophy in women with breast cancer who taking tamoxifen

Public title

Non Hormonal Treatment of Vaginal Atrophy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being married; having stage 1 and 2 breast cancer based on surgery staging; use of tamoxifen; non-use of chemotherapy or radiation during this study; aged under 50 years; with at least one of the symptoms of the self-assessment urogenital atrophy questionnaire; normal Pap smear within the last 3 years; no proven cancer in other organs of the body based on the results recorded in patient records; having sexual activity. Exclusion criteria: vaginal infection (confirmed by Microbiological analysis); abnormal Pap smear; estrogen therapy during the past 8 weeks; unexplained vaginal bleeding; recurrent disease based on the diagnostic results recorded in patient records; smoking cigarette.

Age

From **17 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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

Department of Research and Information Technology, Shiraz University of Medical Sciences, , Zand Blvd., Shiraz, Iran

City

Shiraz

Postal code

72823235 009871

Approval date

2016-06-26, 1395/04/06

Ethics committee reference number

IR.SUMS.REC.1395.63

Health conditions studied

1

Description of health condition studied

: Vaginal Atrophy

ICD-10 code

N95. 3

ICD-10 code description

Diseases of the genitourinary system (N00-N99)

Primary outcomes

1

Description

Vaginal ph

Timepoint

Before intervention, Two weeks after the intervention, Four weeks after intervention, eight weeks after intervention

Method of measurement

PH indicator strip

Secondary outcomes

1

Description

Vaginal cell Maturation

Timepoint

Before intervention, eight weeks after intervention

Method of measurement

Vaginal Maturation Index

2

Description

Symptoms of vaginal atrophy

Timepoint

Before intervention, Two weeks after the intervention, Four weeks after intervention, eight weeks after intervention

Method of measurement

Self-assessment urogenital atrophy questionnaire (UAQ)

Intervention groups

1

Description

Group 1, will be received an intervention that included vaginal suppositories vitamin D (1000 IU Vitamin D in addition to 2 gr the base material), once a day for 2 months

Category

Treatment - Drugs

2**Description**

Group 2, will be received an intervention that included vaginal suppositories vitamin E, (1 mg vitamin E in addition to 2 gr the base material), once a day for 2 months

Category

Treatment - Drugs

3**Description**

Control group, the women in control group will be received placebo vaginal suppositories containing 2 gr base material, (Suppocire AS2), once a day for 2 months

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Motahari Breast Clinic, Shiraz

Full name of responsible person

Zahra keshavarzi

Street address

Midwifery Department, School of Nursing and Midwifery, Nemazee Square, Zand Blvd. Shiraz, Iran.

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. Seyed Basir Hashemi

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

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**

School of Nursing and Midwifery, Shiraz University of Medical Sciences

Full name of responsible person

Dr Roksana Janghorban

Position

Assistant Professor/ PhD

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Web page address**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