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
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Assistant Professor/ PhD
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Person responsible for updating data

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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