

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effects of Vitamin D vaginal suppository on vaginal atrophy in postmenopausal women

Protocol summary

Summary

The aim of this study is to determine the effect of vitamin D vaginal suppository on vaginal atrophy in menopause women. Women enrolled in the study if they are between 44 and 64 years of age with post menopausal at least for one year after the last menstruation. They have excluded from the study if they receive hormonal treatment or intravaginal drug. This study is a double-blind clinical trial and forty-four women selected randomly and divided to two groups. Treatment group received the vitamin D3 200 IU vaginal suppository and control group received placebo vaginal suppository in 8 weeks. They use it every night in first two weeks and every other day in later six-weeks. Vaginal dryness and pale vaginal wall will be assessed in first visit, 2, 4 and 8 weeks. pH and maturation index measured by pH meter and vaginal pop smear respectively, in first visit and eight weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111158109N1**

Registration date: **2012-02-04, 1390/11/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-04, 1390/11/15

Registrant information

Name

Hamdollah Delaviz

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences

Expected recruitment start date

2010-07-27, 1389/05/05

Expected recruitment end date

2012-02-26, 1390/12/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Vitamin D vaginal suppository on vaginal atrophy in postmenopausal women

Public title

The effect of Vitamin D vaginal on vaginal atrophy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged between 16 - 64 years; Laboratory confirmation of menopause; at least one year after the last menstruation. Exclusion criteria: hormonal treatment; intravaginal drug; existence of vaginal infection.

Age

From **44 years** old to **64 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 44

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

Ahvaz University of Medical Sciences

Street address

Golestan highway, Ahvaz Medical Jondi-Shapour University

City

Ahvaz

Postal code

6135715794

Approval date

2011-09-19, 1390/06/28

Ethics committee reference number

Eth-312

Health conditions studied

1

Description of health condition studied

Vaginal atrophy

ICD-10 code

N95.2

ICD-10 code description

Postmenopausal atrophic vaginitis

Primary outcomes

1

Description

Maturation index

Timepoint

two timews, the first and last visit

Method of measurement

pap smear

Secondary outcomes

1

Description

PH

Timepoint

PH

Method of measurement

PH meter

Intervention groups

1

Description

Treatment group received the vitamin D 200 IU vaginal suppository in 8 weeks. They use it every night in first two weeks and every other day in later six-weeks.

Category

Placebo

2

Description

Control group recieved plasbo vaginal suppository in 8 weeks. They use it every night in first two weeks and every other day in later six-weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hifdah septamber treatment center

Full name of responsible person

Parastou Rad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

B-90/0020

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

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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