Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of vitamin D on sexual function in postmenopausal women

Protocol summary

Study aim
Investigating the effect of vitamin D suppositories on the sexual function of postmenopausal women

Design
In this study, 105 postmenopausal women (with inclusion criteria) will be recruited in the study. Using a simple randomization method, participants will be assigned in three study groups. To execute simple randomization method, the assignment sequence will be written before the beginning of the research, and then participants will be assigned in one of three groups of intervention, placebo and control.

Settings and conduct
Participants of the study will be selected among the clients of the comprehensive health centers of Bouyin Zahra.for the purpose of blinding, the assignment and coding sequence will be written by a person who is not in the research group and the codes will be concealed until the end of the analysis. in this way, participants, researcher and analysor will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: postmenopausal women, the absence of other diseases of the gland, such as diabetes and ...
Exclusion criteria: hormone therapy, stressful experience during the last 3 months

Intervention groups
There is three study groups: intervention group receiving vitamin D3 suppositories; control group receiving placebo suppositories, and control group receiving no intervention.

Main outcome variables
Postmenopausal women's Sexual function

General information

Reason for update
The record is updated to report actual start/end recruitment date and trial completion date.

Acronym

IRCT registration information
IRCT registration number: **IRCT20180704040346N1**
Registration date: **2018-10-13, 1397/07/21**
Registration timing: **prospective**

Last update: **2022-01-06, 1400/10/16**
Update count: **1**

Registration date
2018-10-13, 1397/07/21

Registrant information

Name
Zinat Sarebani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3378 2521

Email address
z.sarebani@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-02-20, 1397/12/01

Actual recruitment start date
2019-08-01, 1398/05/10

Actual recruitment end date
2020-05-30, 1399/03/10

Trial completion date
2020-08-30, 1399/06/09

Scientific title
Effect of vitamin D on sexual function in postmenopausal women

Public title
Effect of vitamin D supplements on sexual function

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

One year after experiencing the last menstrual cycle The absence of other diseases of the glands such as Kushnig disease, diabetes, ..

Exclusion criteria:

Use of vaginal drugs Having a moderate to severe infection Hormone Therapy Stressful experience during the last quarter There are abnormalities or surgery

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Actual sample size reached: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants of the study will be selected among the clients of the comprehensive health centers of Boyeen Zahra, Qazvin. Using simple randomization method, random allocation of samples will be done in three groups. for simple randomization method, the assignment sequence will be written before the start of the research. Given that the three groups will be studied, each letter will be assigned to one group (A suppository of vitamin D3, B group of placebo and C of the control group with routine care). Randomization is performed using the random allocation software. According the assignment sequence, the type of intervention will be written inside Opaque envelopes. Questionnaires will be encoded with the same sequence. In this case, a questionnaire with the same code will be completed for the person receiving the code 1 intervention.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study triple blinding will be performed. For this purpose, suppositories containing the drug and placebo will be prepared by the pharmaceutical company and will be packed anonymously with codes, so that the participants, the provider and the assessor (researcher) and the statistical analyst will not know the suppository type associated with each code (triple blinding). After the study and statistical analysis, the drug codes will be received from the pharmaceutical company.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences

Street address

Bahonar blevard, Qazvin university of Medical Science, School of Nursing & Midwifery

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2018-09-16, 1397/06/25

Ethics committee reference number

IR.QUMS.REC.1397.117

Health conditions studied

1

Description of health condition studied

sexual function

ICD-10 code

F66.2

ICD-10 code description

N95. Sexual relationship disorder

Primary outcomes

1

Description

Sexual Function

Timepoint

Before the intervention, immediately after the intervention, one and two months after the end of the intervention

Method of measurement

using Female Sexual Function Index (FSFI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The vaginal suppository of vitamin D is administered at a dose of 1000 units for 8 weeks; one suppository every night in the first two weeks, and one suppository every two nights the next six weeks. The

main base of the suppository is mono, di, and triglyceride named AM-15 suppository synthesized by Gattefosse France. Base melting point is 34-36 degrees. Suppositories will be produced by melting and molding under the supervision of a pharmacist and will be produced by pharmaceutical experts from the pharmaceutical laboratory of the Faculty of Pharmacy of Mashhad. Each drug suppository weighs 1 gram and contains 1000 units of vitamin D. The superstructures have a sufficient mechanical strength and a smooth, uniform, whitewashed surface. After making suppositories, put them in the right amount in tight plastic packaging and placed in plastic containers at a temperature below 25 degrees, preferably kept in the refrigerator

Category

Treatment - Drugs

2

Description

Control group: placebo vaginal suppositories will be administered in placebo group with a similar treatment protocol of intervention group. Pharmacological properties and the manufacturing process of placebo suppositories are quite similar to the intervention group suppositories, except that in placebo supplements, the vitamin D will not be added.

Category

Placebo

3

Description

Control group: No intervention will be implemented. This group will receive routine heath cares for elders.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers of Boyin Zahra

Full name of responsible person

Zinat Sarebani

Street address

Boyeen Zahra Health Care Network

City

Boyin Zahra

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Qazvin

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34137344345

Phone

+98 28 3422 2229

Email

z.sarebani@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zinat Sarebani

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zinat Sarebani

Position

Master's degree in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zinat Sarebani

Position

Master's degree in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zinat Sarebani

Position

Master of Midwifery Counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Phone

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data from the research results in the post-publication of the resulting research paper will be uploaded as a supplementary file of the original files

When the data will become available and for how long

After the end of the study, and simultaneously publishing the results

To whom data/document is available

Free access

Under which criteria data/document could be used

In case of correspondence with the author and the need to analyze beyond the objectives of the present study

From where data/document is obtainable

Corresponding with the responsible person

What processes are involved for a request to access data/document

To email z.sarebani@qums.ac.ir/Mid2017sarebani@gmail.com

Comments