

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Feb 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 analyst 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 are 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 health 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

**Province**

Qazvin

**Postal code**

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**

Boyeen Zahra Health Care Network

**City**

Boyeen Zahra

**Province**

Qazvin

**Postal code**

3413744345

**Phone**

+98 28 3422 2229

**Email**

z.sarebani@qums.ac.ir

**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

**Street address**

Boyeen Zahra Health Care Network

**City**

Bouyin Zahra

**Province**

Qazvin

**Postal code**

3413744345

**Phone**

+98 28 3422 2229

**Email**

z.sarebani@qums.ac.ir

## 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

**Street address**

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**Province**

Qazvin

**Postal code**

3413744345

**Phone**

+98 28 3422 2229

**Email**

z.sarebani@qums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Zinat Sarebani

**Position**

Master of Midwifery Counseling

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Boyeen Zahra Health Care Network

**City**

Boyeen Zahra

**Province**

Qazvin

**Postal code**

3413744345

**Phone**

+98 28 3422 2229

**Email**

z.sarebani@qums.ac.ir

## 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**