Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Assessment of effectiveness of oral vitamin D3 on Bacterial vaginosis in women in fertility ages

Protocol summary

Summary

A population of 190 women who refer to Gynecology Clinic will be investigated in this clinical trial after being informed and signing the written consent. The subjects' eligibility for this research will be examined by screening the PH of their vaginal discharge, laboratory analysis of vaginal discharge slides for detection of vaginosis bacterial, and measurement of Vitamin D concentration in blood sample serum. Subjects passing the history, clinical and lab tests will take part in random phase and will be blindly divided in two groups: intervention and control (researcher, research unit and statistician will not be informed). For intervention group, daily drops of 2000-unit vitamin D3 dissolved in sesame oil and for the control group, placebo (sesame oil only) with the same appearance, color, taste and smell of intervention group will be advised for 15 weeks (105 days/3.5 months). At the end of the intervention, bacterial vaginosis and vitamin D concentration will be evaluated in samples.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105096284N2**
Registration date: **2011-09-04, 1390/06/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-09-04, 1390/06/13

Registrant information

Name

Maryam Modarres

Name of organization / entity

Tehran university of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6656 8142

Email address

modarres@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2012-01-20, 1390/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of effectiveness of oral vitamin D3 on Bacterial vaginosis in women in fertility ages

Public title

Assessment of effectiveness of oral vitamin D3 on Bacterial vaginosis in women in fertility ages

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Ages 18-35; Stability in medical condition among 6 months later; Lack of Pathological obesity; Not using tobacco; Lack of history of hypercalcemia, nephrolitiasis or sarcoidosis; Lack of current pregnancy; Lack of recent history of hospitalization; Absence of liver or kidney disorder; current malignancy or malabsorption; Lack of immune suppression, or those drugs that will interfere with

vitamin D metabolism, such as phenytoin and carbamazepine; Not taking vitamin D supplements meet; Lack of clinical bacterial vaginosis; Lack of normal amounts of vitamin D in first assessment; Detection of asymptomatic bacterial vaginosis with nugent test Exclusion criteria: Unwillingness to continue the use of drug; pregnancy occurred; Drug allergy symptoms such as gastrointestinal symptoms; Vaginal infection symptoms like foul-smelling discharge; Use of drug non according to the pharmacist recommendation

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **190**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple 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 Tehran University of Medical sciences

Street address
f 6th, Center organization of university, edge of Qods avenue, Keshavarz blvd

City
Tehran

Postal code

Approval date
2011-06-19, 1390/03/29

Ethics committee reference number
130/1312/د

Health conditions studied

1

Description of health condition studied
Bacterial vaginosis

ICD-10 code
N76.0

ICD-10 code description
Acute vaginitis

Primary outcomes

1

Description
Bacterial vaginosis

Timepoint
105 days

Method of measurement
Nugent test

Secondary outcomes

1

Description
Concentration of vitamin D in serum

Timepoint
105 days

Method of measurement
Lab test

Intervention groups

1

Description
Placebo drops of Sesame oil only, with the shape, taste, color & smell as same as intervention group which is prescribed 2 drops per day for 105 days

Category
Placebo

2

Description
Oral drops of vitamin D3 which is prescribed Two drops (2000 IU vitamin D) per day for 105 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital gynecology Clinic

Full name of responsible person
Mahshid Taheri

Street address
Gynecology clinic, Hospital complex of Imam Khomeini, Tohid square

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran University of Medical sciences

Full name of responsible person
Research assistant of Tehran University of Medical sciences (Dr. Akbar Fotoohi)

Street address
5th floor,Central building of Tehran University of Medical sciences, edge of Qods Av, Keshavarz blvd, Tehran

City
Tehran

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, Tehran 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
Tehran University of Medical sciences

Full name of responsible person
Dr. Masud Yunesian

Position
Research Affairs

Other areas of specialty/work

Street address
601th Unit, 6th floor, Central Organization of Tehran University of Medical sciences, Qods ave, Keshavarz Blvd

City
Tehran

Postal code

Phone
+98 21 8163 3619

Fax

Email
younesian@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Faculty of Nursing & Midwifery

Full name of responsible person
Maryam Modarres

Position
MSc Midwifery

Other areas of specialty/work

Street address
Faculty of Nursing & Midwifery, Tohid square

City
Tehran

Postal code

Phone
+98 912 388 0257

Fax

Email
modarres@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

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