Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Study of the effect of high dose vitamin D3 on improvement of bacterial vaginosis in vitamin D deficient women

Protocol summary

Study aim
Evaluation of the effect of high dose vitamin D3 supplementation on improvement of bacterial vaginosis in women with vitamin D deficiency

Design
Parallel group, open label, randomized, phase 3 controlled trial of 40 patients

Settings and conduct
This study is an open label clinical trial that will be done in a Gynecology clinic in Ṡhahid Motahari hospital. Patients will be randomly assigned to the vitamin D3 or control group. Outcomes will be assessed at the initiation of the study and 14 days after completion of treatment.

Participants/Inclusion and exclusion criteria
Premenopausal women aged> 16 years with serum 25 (OH) D concentration of < 20 ng / ml and bacterial vaginosis will be included. Women with any of the following conditions will be excluded: concurrent vaginal candidiasis or trichomoniasis, being in the bleeding phase of menstruation, systemic or vaginal use of antibiotics in the past 2 weeks, pregnancy and lactation.

Intervention groups
Intervention group: Patients will receive metronidazole tablet 500 mg twice daily for one week. Moreover, patients will receive a 50000 IU soft gel capsule of vitamin D per day for 5 days. Control group: participants will only receive metronidazole tablet 500 mg twice daily for one week.

Main outcome variables
Number of clinical outcome responders, defined as patients with normal vaginal discharge, vaginal secretions pH < 4.5, negative whiff test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150609022637N7**
Registration date: **2020-06-20, 1399/03/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-20, 1399/03/31**
Update count: **0**

Registration date
2020-06-20, 1399/03/31

Registrant information

Name
Naemeh Nikvarz

Name of organization / entity
Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-28, 1399/02/09

Expected recruitment end date
2020-07-21, 1399/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of high dose vitamin D3 on improvement of bacterial vaginosis in vitamin D deficient women

Public title

Study of the effect of vitamin D3 on improvement of bacterial vaginosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Premenopausal women aged> 16 years Serum 25 (OH) D concentration of < 20 ng / ml Having bacterial vaginosis

Exclusion criteria:
Concurrent vaginal candidiasis or trichomoniasis Being in the bleeding phase of menstruation Systemic or vaginal use of antibiotics in the past 2 weeks Pregnancy Lactation

Age
From **16 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization with randomly selected block sizes of 4,6 and 8. For example a block size of 4 randomizes 4 participants, and each participant is assigned to one of the intervention groups based on the arranged series of intervention groups in this block.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Research assistance office of Kerman University of Medical Sciences, Ebne-Sina street

City
Kerman

Province
Kerman

Postal code
7619813159

Approval date
2020-04-27, 1399/02/08

Ethics committee reference number
IR.KMU.REC.1399.102

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
Number of patients respond clinically defined as those with normal vaginal discharge, vaginal secretion pH < 4.5, and negative whiff test

Timepoint
At baseline and 14 days after completion of treatment

Method of measurement
Self reported characteristics of vaginal discharge including odor and color of discharge, measurement of pH of vaginal secretion with pH strips, for performing the whiff test, several drops of 10% potassium hydroxide is added to the sample of vaginal discharge. Release of a fish amine odor indicates a positive whiff test.

Secondary outcomes

1

Description
Percentage of clue cells on microscopic examination of the vaginal wet mount

Timepoint
At baseline and 14 days after completion of the study

Method of measurement
Microscopic examination of vaginal discharge

2

Description
Serum concentration of 25 (OH) vitamin D

Timepoint
At baseline and end of the study

Method of measurement
Laboratory tests in hospital laboratory

Intervention groups

1

Description
Intervention group: Patients will receive metronidazole tablet 500 mg twice daily for one week. Moreover,

patients will receive a 50000 IU soft gel capsule of vitamin D per day for 5 days.

Category

Treatment - Drugs

2

Description

Control group: participants will only receive metronidazole tablet 500 mg twice daily for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Motahary hospital

Full name of responsible person
Sima Mousavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

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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

Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
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Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Clinical pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable