

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Shahid 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

Country

Iran (Islamic Republic of)

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+98 34 3132 5017

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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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Kashani street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

Naemeh Nikvarz

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Clinical pharmacy

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Person responsible for updating data

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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