Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of vaginal consumption of vitamin C supplementation on the improvement of the role of metronidazole in the treatment of patients with bacterial vaginitis

Protocol summary

Study aim
Improving the treatment of bacterial vaginitis using Vitamin C

Design
Clinical trail have two parallel double-blind randomized group

Settings and conduct
This study will be make in Imam Reza Clinic of Kashan University of Medical Sciences in order to evaluate the vitamin c in improvement of bacterial vaginitis that paints randomized two group of vitamin c and placebo and will be evaluated for clinical and laboratory symptoms before and after treatment.

Participants/Inclusion and exclusion criteria
Include:women with bacterial vaginitis base on clinical symptoms and laboratory findings Exclude: Patients with immunodeficiency or HIV positive women with genital and urinary tract infections. Menstruation at the time of attendance. Pregnancy. Vitamin C sensitivity Women who do not allow pelvic examination. Taking any vaginal drugs, antibiotics, and immune-suppressing drugs and exogenous hormones, including oral contraceptives, during the 2 weeks prior to the study. Having intercourse or using vaginal douche within the last 24 hours

Intervention groups
Intervention group treated with metronidazole orally twice daily (morning and night) for 7 days with vaginal suppository containing 250 mg vitamin C for 7 days. Control group treated with metronidazole orally twice daily (morning and night) for 7 days with placebo suppository for 7 days.

Main outcome variables
Changes in the clinical symptoms and direct smear of the patient

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160905029710N2**
Registration date: **2020-01-29, 1398/11/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-29, 1398/11/09**
Update count: **0**

Registration date
2020-01-29, 1398/11/09

Registrant information

Name
Mehdi Nazeri

Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-18, 1398/10/28

Expected recruitment end date
2020-07-05, 1399/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of vaginal consumption of vitamin C supplementation on the improvement of the role of metronidazole in the treatment of patients with bacterial vaginitis

Public title
Effect of vaginal consumption of vitamin C supplementation in the treatment bacterial vaginitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women with bacterial vaginitis base on clinical symptoms and laboratory findings

Exclusion criteria:
Patients with immunodeficiency or HIV positive Women with genital and urinary tract infections Menstruation at the time of attendance Pregnant Vitamin C sesitivity Women who do not allow pelvic examination Taking any vaginal drugs, antibiotics, and immune-suppressing drugs and exogenous hormones, including oral contraceptives, during the 2 weeks prior to the study. Having intercourse or using vaginal douche within the last 24 hours

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by simple method and using random numbers generated by computer software (Stat Trek software). In this method the computer selects random numbers. with consideration of numbers, the two groups are randomized.Patients are divided into two groups of 30 intervention and 30 control groups and both groups are blinded to complementary therapy.

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo will be used to achieve participants,Care provider and investigators will be masking. The researchers and patients will be concealed until the final analyses by a trained staff

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
5th of Qotb –e Ravandi Blvd. P.O.Box: 8715988141, Kashan, IRAN

City
Kashan

Province
Isfehan

Postal code
8715988141

Approval date
2019-12-02, 1398/09/11

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1398.101

Health conditions studied

1

Description of health condition studied
Bacterial Vaginitis

ICD-10 code
B96

ICD-10 code description
Other bacterial agents as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Bacterial Vaginitis

Timepoint
Clinical signs and bacterial composition of direct smear will be assessed at baseline (before intervention) and 7 days after administration of Vitamin C.

Method of measurement
Questionnaire containing demographic information and clinical symptoms

2

Description
Improve vaginal bacterial composition

Timepoint
Bacterial composition of direct smear at baseline (before intervention) and 7 days after intervention.

Method of measurement

Direct smear assessment before treatment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with bacterial vaginitis treated with vaginal vitamin C 250 mg daily for seven days and clinical and laboratory symptoms will be assessed before and after treatment.
Category
Treatment - Drugs

2

Description
Control group: Patients with bacterial vaginitis treated with placebo daily for seven days and clinical and laboratory symptoms will be assessed before and after treatment.seven days and evaluation of clinical and laboratory symptoms after treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Clinic, Beheshti Ave, Kashan
Full name of responsible person
Dr. Zahra Vahedipoor
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamid Reza Banafshe
Street address
5th of Qotb –e Ravandi Blvd. P.O.Box: 8715988141, Kashan, IRAN
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr. Zahra Vahedipoor
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Data can be shared after people are unrecognizable

When the data will become available and for how long
12 months after publish

To whom data/document is available
Only for academic researchers only

Under which criteria data/document could be used
Help to patient treatment

From where data/document is obtainable
مدیر اجرایی طرح

What processes are involved for a request to access data/document
پس از درخواست کتبی و بررسی صحت در خواست و کور نمودن مشخصات بیماران

Comments