

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 trial 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

Department of Medical Parasitology and Mycology,
Medical faculty, kashan university of medical scien

Country

Iran (Islamic Republic of)

Phone

+98 31 5555 1112

Email address

nazeri_me@kaums.ac.ir

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

Isfahan

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

Street address

Imam Reza Clinic, Beheshti Ave, Kashan

City

Kashan

Province

Isfahan

Postal code

1134845764

Phone

+98 31 5546 6301

Email

zahravahedpoor@g.commail

Web page address

<http://kaums.ac.ir/>

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

City

Kashan

Province

Isfahan

Postal code

8814187159

Phone

+98 31 5557 8011

Email

banafshe57@hotmail.com

Web page address

<http://kaums.ac.ir/>

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

Gynecology and Obstetrics

Street address

Obstetrics and Gynecology, Kashan University of
Medical Sciences, Kashan, Iran

City

Kashan

Province

Isfahan

Postal code

8814187159

Phone

009836155540023

Email

zahravahedpoor@g.commail

Web page address

<http://medicine.kaums.ac.ir/Default.aspx?PageID=337>

Person responsible for scientific 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

Gynecology and Obstetrics

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Phone

009836155540023

Email

zahravahedpoor@g.commail

Web page address

<http://medicine.kaums.ac.ir/Default.aspx?PageID=337>

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mehdi Nazeri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Mycology

Street address

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

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

009855540026

Email

mehdinazeri@yahoo.com

Web page address

<http://medicine.kaums.ac.ir/Default.aspx?PageID=90>

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