Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of curcumin tablets with metronidazole tablets on the treatment of bacterial vaginosis

Protocol summary

Study aim

Comparison of the effect of curcumin tablets with metronidazole tablets on the treatment of bacterial vaginosis

Design

This study is a clinical trial. By referring to women's outpatient clinics in Alborz province, 90 eligible people are selected to enter the study. Without blinding, sampling is done by simple random sampling. One group is given metronidazole 500 tablets and the other group is given 40 nano curcumin capsules. Participants in both groups come 2 weeks after taking the medication to check for improvement.

Settings and conduct

Methods: If the disease is confirmed in eligible individuals, patients will be randomly divided into two groups of metronidazole 500 tablets and curcumin nano 40 capsules (every 12 hours for 7 nights).collection place: Women's outpatient clinics in Alborz province

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age 18- 49 years 2. Being married 3- Lack or absence 4 - No pregnancy and lactation 5- Proof of bacterial vaginosis 6- Not having allergies to curcumin (turmeric) or other medicinal plants 7. No history of known chronic disease 8. Not using herbal medicines and chemicals related to the treatment of genital infections during the last two weeks 9 - No active gastrointestinal ulcers and also no bile problems and gallstones Exclusion criteria: 1- Getting pregnant during treatment 2. The presence of other vaginal infections 3. Complications or allergies to curcumin 4. The reluctance of the participant to continue the research

Intervention groups

Intervention group: 45 people with bacterial vaginosis who use curcumin nano 40 capsule instead of metronidazole treatment. Control group: 45 people with bacterial vaginosis who receive routine treatment with metronidazole 500.

Main outcome variables

Improve the symptoms of bacterial vaginosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120414009463N61**
Registration date: **2020-12-02, 1399/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-02, 1399/09/12**
Update count: **0**

Registration date

2020-12-02, 1399/09/12

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

behboodi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of curcumin tablets with metronidazole tablets on the treatment of bacterial vaginosis

Public title
Comparison of the effect of curcumin tablets with metronidazole tablets on the treatment of bacterial vaginosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1- Age 18- 49 years 2. Being married 3 - Do not be menopause 4 - No pregnancy and lactation 5- proof of bacterial vaginosis 6- Not having allergies to curcumin (turmeric) or other medicinal plants 7. No history of known chronic disease 8. Not using herbal medicines and chemicals related to the treatment of genital infections during the last two weeks 9 - No active gastrointestinal ulcers and also no bile problems and gallstones
Exclusion criteria:
1.Pregnancy during treatment 2. The presence of other vaginal infections 3. Complications or allergies to curcumin 4. The reluctance of the participant to continue the research 5 - not following the correct method of treatment (forgetting to take medicine for more than one night) 6- Use of systemic antibiotics to treat non-bacterial systemic infection during treatment
Age
From **18 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling of this study will be random using block method. In this way, all eligible people enter the study after providing complete explanations and obtaining informed consent and are randomly placed in one of the two intervention or control groups with a quadruple blocking method. In this way, we will consider the letter A for the intervention group and the letter B for the control group. Then write all the permutation compounds of the letters A, A and B, B, which are 6 combinations (AABB for combination 1, ABBA for combination 2, etc.) and from combinations 1 to 6, a combination will be randomly selected. . For example, if combination 1 is selected, it means that the first and second people will be in the intervention group and the third and fourth people will be in the control group. Sampling will continue until the desired number of samples in each group is reached.

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 Tehran University of Medical Sciences and Health Services
Street address
Keshavarz Boulevard, corner of Quds Street, central building
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2019-12-22, 1398/10/01
Ethics committee reference number
IR.TUMS.FNM.REC.1399.093

Health conditions studied

1

Description of health condition studied
Bacterial vaginosis treatment
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Vaginosobacterial treatment with nanocurcumin 40 capsules
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The primary outcome is the percentage of people who have improved after taking oral curcumin tablets to treat bacterial vaginosis.
Timepoint
Periods of disease evaluation, before the intervention

and two weeks after starting metronidazole and curcumin tablets

Method of measurement

Existence of three of Amsel's four standard signs

Secondary outcomes

empty

Intervention groups

1

Description

.Intervention group: Study participants who meet the inclusion criteria are treated with 40 nanocurcumin capsules every 12 hours for one week.

Category

Treatment - Drugs

2

Description

Control group: Participants in the study who meet the inclusion criteria are treated with metronidazole 500 tablets every 12 hours for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's outpatient clinics in Alborz province

Full name of responsible person

Sakineh Mohammadi

Street address

School of Nursing and Midwifery - Tehran University of Medical Sciences - Nosrat Sharghi - Tohid Square - Tehran - Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Saeed Goodarzi

Street address

Tehran, Enghelab Square, 16 Azar St., Tehran University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

medical University Tehran

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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Behboodi Moghadam

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

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Position
Masters student

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Bachelor

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Midwifery

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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
I have not decided yet - the release schedule is not clear yet

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available