Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of vaginal tablets of vitamin C with metronidazole on treatment of bacterial vaginosis ,clinical trials.

Protocol summary

Summary

The purpose of this study is diagnosis the effects of vitamin C vaginal tablet plus oral metronidazole on treatment of bacterial vaginosis. According to this object ,a randomized double blind control trial, 160 non-pregnant, non breastfeeding women aged between 18 to 45 years old with the randomized allocation, can be considered in a way of two groups of 80 ‘s members. After bacterial vaginosis diagnosis by Amsel and Nagent criteria, intervention group will receive vitamin C vaginal tablet 250 mg with oral metronidazole (prescribed with the dose of 500 mg twice a day) during 7 days and control group will receive placebo vaginal tablet with oral metronidazole (with the same dose). All of participants will be followed days of 10 ± 1 and 30 ± 3 after treatment and final diagnosis will be done according to clinical and laboratory criteria .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042521917N3**
Registration date: **2015-05-30, 1394/03/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-05-30, 1394/03/09

Registrant information

Name

Sevil Hakimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences. Women’s Reproductive Health Research Center

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of vaginal tablets of vitamin C with metronidazole on treatment of bacterial vaginosis ,clinical trials.

Public title

Effectiveness of vaginal tablets of vitamin C with metronidazole on treatment of bacterial vaginosis. (A randomised , double blind , control trial)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: non-pregnant and non breastfeeding married women age between 18 -45 Years Old,diagnosis of bacterial vaginosis with contemporary presence of at least three out of four Amsel criteria and gain score 4 to 6 with clue cells or score 7 to 10 without clue cells in Nugent scoring system, have willing to participate to study , possibility to attending center in schedule time for post treatment follow up , husband’s monogamous ,

Filling the Informed Consent Form; Exclusion criteria: chronic disease , consumption of vaginal medication or douching during the recent weeks , Immune deficiency syndrome, consumption of antibiotic during the recent weeks , consumption of rifampin –phenytoin-phenobarbital and any anticoagulant agents , other vaginal infections ,presence of unknown vaginal bleeding .

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization with the randomized allocation

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Faculty of Nursing & Midwifery, South Shariaty Street

City
Tabriz

Postal code
3417174914

Approval date
2015-04-13, 1394/01/24

Ethics committee reference number
TBZMED.REC.1394.5

Health conditions studied

1

Description of health condition studied
Bacterial Vaginosis

ICD-10 code
N70-N77

ICD-10 code description
Inflammatory diseases of female pelvic organs

Primary outcomes

1

Description
Clinical and laboratory criteria based on Amsel and Nugent scoring system .

Timepoint
Before intervention, 10 ± 1 and 30 ± 3 days after treatment.

Method of measurement
Measured by clinical measurements of diseases and laboratory tests.

2

Description
Malodon discharge

Timepoint
Before intervention, 10 ± 1 and 30 ± 3 days after treatment.

Method of measurement
Measured by asking from patient

3

Description
Itching

Timepoint
Before intervention, 10 ± 1 and 30 ± 3 days after treatment.

Method of measurement
Measured by asking from patient

4

Description
Dyspareunia

Timepoint
Before intervention, 10 ± 1 and 30 ± 3 days after treatment.

Method of measurement
Measured by asking from patient

5

Description
Having fishy smell during sexual intercourse

Timepoint
Before intervention, 10 ± 1 and 30 ± 3 days after treatment.

Method of measurement
Measured by asking from patient

Secondary outcomes

1

Description
The vaginal PH change
Timepoint
Before intervention, 10 ± 1 and 30 ± 3 days after treatment.
Method of measurement
PH paper scale

2

Description
Change in Clue Cells
Timepoint
Before intervention, 10 ± 1 and 30 ± 3 days after treatment.
Method of measurement
Measured by laboratory tests.

Intervention groups

1

Description
Intervention group will receive vitamin C vaginal tablet 250 mg which produced by Faculty of Medicine Pharmaceutical group in Tabriz university of medical science with oral metronidazole (prescribed with the dose of 500 mg twice a day) during 7 days .
Category
Treatment - Drugs

2

Description
Control group will receive placebo vaginal tablet along with oral metronidazole (prescribed with the dose of 500 mg twice a day) during 7 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Samenol Aeme Hospital
Full name of responsible person
Toktam Dokhanchi
Street address
Imam khomeini square, Mashhad
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences. Women's Reproductive Health Research Center
Full name of responsible person
Parvin Mostafa Ghare Baghi
Street address
Alzahra Hospital, South Artesh Ave.
City
Tabriz
Grant name
_
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences. Women's Reproductive Health Research Center
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Sevil Hakimi
Position
PhD of reproductive health
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty