Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Sep 2026

The comparison of the effects of garsin tablet (made of garlic) and metronidazole tablet on treatment of bacterial vaginosis

Protocol summary

Summary

This study compares the effects of garsin tablet (made of garlic) and metronidazole tablet on treatment of bacterial vaginosis. This study is a randomized clinical trial (single blind) which is conducted on 140 married women, aged 18 – 44years old, with single partner whose infection with bacterial vaginosis is diagnosed through clinical Amsel criteria and laboratory Nugent criteria. Identified patients with cervicitis, tricamona or candidiadis infections are excluded from the study. They should not use IUD. Also they should not use antibiotics, vaginal drug or immunosuppressive drugs in recent fourteen days. They should not be pregnant, lactating or menopause. They should not have mental retardation or known physical disease; suffering from thyroid disease; coagulation disorders; diabetes and autoimmune diseases. Exclusion criteria: Not tolerate any form of drug or discontinuation for at least 48 hours, become pregnant during treatment, forcing the use of antibiotics during treatment. The participants are randomly divided into two groups of 70 persons each: garsin tablet (two 500 mg tablets, twice a day) and metronidazole tablet (two 250 mg tablets, twice a day). Treatment period in each group lasts seven days. Clinical Amsel criteria and laboratory Nugent criteria will be again checked 7 to 10 days after beginning of the treatment period and the side - effects will be registered. Independent variables in this study are garsin tablet and metronidazole tablet and the dependent variable is bacterial vaginosis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207153226N4**
Registration date: **2013-12-20, 1392/09/29**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-12-20, 1392/09/29

Registrant information

Name

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Name of organization / entity

Shahid Beheshti University of Medical Scenices

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Recruitment status

Recruitment complete

Funding source

The International Branch of shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-12-16, 1392/09/25

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effects of garsin tablet (made of garlic) and metronidazole tablet on treatment of bacterial vaginosis

Public title

The comparison of the effect of garsin and metronidazole on bacterial vaginosis

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: married women; aged 18-44 years old, with single partner whose infection with bacterial vaginosis is diagnosed through clinical Amsel criteria and labratory Nugent criteria (Patients identified with cervicitis tricamona or candidiadis infections are excluded from the study); they should not use IUD. Also they should not use antibiotics, vaginal drug or immunosuppressive drugs in recent fourteen days. During clinical examination they should not have any breakthrough bleeding or menstrual period. They should not be pregnant, lactating or menopause. They should not have mental retardation or known physical disease; suffering from thyroid disease; coagulation disorders; diabetes and autoimmune diseases. Exclusion criteria: not tolerate any form of drug or discontinuation for at least 48 hours, become pregnant during treatment, forcing the use of antibiotics during treatment.
Age
From **18 years** old to **44 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The International Branch of Shahid Beheshti university of medical sciences & health sciences
Street address
No.19, Adjacent to Hemmat bridge, shaheed Abbaspour ave, Valiasr street,Tehran.Iran
City
Tehran
Postal code
7413934358
Approval date
2013-10-07, 1392/07/15
Ethics committee reference number
2880/116

Health conditions studied

1

Description of health condition studied
Bacterial vaginosis infection
ICD-10 code
N77
ICD-10 code description
Vulvovaginal ulceration and inflammation in diseases classified elsewhere

Primary outcomes

1

Description
Amsel criteria
Timepoint
Before the intervention, 7-10 days after begining of treatment
Method of measurement
Amsel have 4 criteria: key cells in the wet mount vaginal sample Vaginal dyscharge thin and white uniform - gray, white or yellowish, Vaginal pH equal to or greater than 4/5, positive whiff test. If at least 3 of the 4 cases mentioned above is positive, bacterial vaginosis is brought on .

2

Description
Nugent criteria
Timepoint
Before the intervention, 7-10 days after beginning treatment
Method of measurement
These criteria are based on the observation lactobacil and other morphotype (Gardnerella vaginalis and Mobiluncus forms) are rated from zero to 10 points, a total score of 7-10 means abnormal vaginal flora (bacterial vaginosis), grades 4-6 (Intermediate) in this study means abnormal vaginal flora. normal flora score is 0-3.

Secondary outcomes

1

Description
bacterial vaginosis infection
Timepoint
Before the intervention, 7-10 days after beginning treatment
Method of measurement
Clinical complaint questionnaires are completed by samples (itching, burning, abnormal discharge, smelly discharge).

Intervention groups

1

Description
One group Metronidazole 250 mg tablet, twice daily 500 mg (every 12 hours) with food for 7 days
Category
Treatment - Drugs

2

Description
the other group Garsin 500 mg tablet, twice daily 1000 mg (every 12 hours) with meal for 7 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Resalat Health Center
Full name of responsible person
farnaz mohammadzadeh
Street address
Taleb amoli street, daryeye 38 ave.
City
Amol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The International Branch of Shahid Beheshti university of medical sciences
Full name of responsible person
Mrs Dr Ghanati
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No.19, Adjacent to Hemmat bridge, shaheed Abbaspour ave, Valiasr street,Tehran.Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The International Branch of Shahid Beheshti university of medical sciences
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
The International Branch of Shahid Beheshti university of medical sciences
Full name of responsible person
Farnaz Mohammadzadeh
Position
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Other areas of specialty/work
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Person responsible for updating data

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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