

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, trichomonas or candidiasis 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

Mahrokh Dolatian

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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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 laboratory Nugent criteria (Patients identified with cervicitis trichomonas or candidiasis 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, shahed 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 beginning of treatment

Method of measurement

Amsel have 4 criteria: key cells in the wet mount vaginal sample Vaginal discharge 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

Street address

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

M.Sc Student of Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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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