# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Clinical trial of comparison the effect of tinidazole and metronidazole tablet for treatment and recurrence of bacterial vaginosis in women of reproductive age

### Protocol summary

**Summary**

This study is a double-blind randomized clinical trial that compare effect of tinidazole and metronidazole oral tablet for treatment and recurrence of bacterial vaginosis. In this study, 110 nonpregnant married women aged between 15-45 years with bacterial vaginosis were configurated in two treatment groups. Clinical diagnosis is based on the combination of any three of the following four Amsel criteria: thin homogeneous vaginal discharge, PH of vaginal discharge more than 4.5, positive wiff test, clue cells on microscopic examination of vaginal fluid. Tinidazole tablet was given to one group (2 g daily for two days) and metronidazole tablet was given to another group (500 mg twice daily for seven day). Patients were followed after two and four weeks. Improvement was defined as being less than three Amsel criteria.

### General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2012073110457N1**
Registration date: **2013-03-20, 1391/12/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2013-03-20, 1391/12/30

**Registrant information**

**Name**

zeinab Rabee

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences,Ahvaz,Iran

**Country**

Iran (Islamic Republic of)

**Phone**

+98 61 1373 8383

**Email address**

rabee@ajums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Ahvaz Jundishapur University of Medical Sciences,Ahvaz,Iran

**Expected recruitment start date**

2012-09-22, 1391/07/01

**Expected recruitment end date**

2013-01-19, 1391/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Clinical trial of comparison the effect of tinidazole and metronidazole tablet for treatment and recurrence of bacterial vaginosis in women of reproductive age

**Public title**

The effect of tinidazole for treatment and recurrence of bacterial vaginosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: age 45-15 years, married women, diagnosis of bacterial vaginosis by clinical signs and diagnostic tests, accept the use of condoms during treatment. Exclusion criteria: associated with Candida vaginitis and trichomonas, Pregnancy, consume

antibiotics at the same time or within two weeks and using the vaginal cream, metronidazole used simultaneously to any cause, having a chronic disease and diabetes, Immunosuppression or immune-lowering medication use, having cervicitis, chronic bacterial vaginosis

**Age**
From **15 years** old to **45 years** old

**Gender**
Female

**Phase**
2

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **110**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**
For blinding the study, drug usage was explained to another person and was asked her to package drug similarly and naming them for example drug a , drug b, then give the first suitable patient drug a and next patient drug b,then explain drug usage to them. At this way , drug were given alternately and ask patients refer to us after two and four weeks for following up the treatment and recurrence

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ahvaz Ethics committee of Jundishapur University of Medical Sciences,Ahvaz,Iran

**Street address**
Golestan Street-Ahvaz Jundishapur University of Medical Sciences,Ahvaz,Iran

**City**
Ahvaz Jundishapur University of Medical Sciences,Ahvaz,Iran

**Postal code**
61357-15794

**Approval date**
2012-07-20, 1391/04/30

**Ethics committee reference number**
eth-535

## Health conditions studied

### 1

**Description of health condition studied**
Bacterial vaginosis

**ICD-10 code**
N76.0

**ICD-10 code description**
Acute vaginitis

## Primary outcomes

### 1

**Description**
Vaginal discharge

**Timepoint**
Pre intervention, two and four weeks after treatment

**Method of measurement**
Observation

### 2

**Description**
Vaginal PH

**Timepoint**
Pre intervention.two and four weeks after treatment

**Method of measurement**
Universal indicator paper

### 3

**Description**
Wiff test

**Timepoint**
Pre intervention,two and four weeks after treatment

**Method of measurement**
KOH

### 4

**Description**
Clue cell

**Timepoint**
Pre intervention, two and four weeks after treatment

**Method of measurement**
Pap smear

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention 1, Tinidazole, oral tablet, 2 g daily for two day,brand name:Tindamax, Manufacturer:Kimidaru

**Category**
Treatment - Drugs

**2**

**Description**
Intervention 2, Metronidazole, oral tablet, 500 mg, twice daily for seven day, brand name: Metromax , Manufacturer:kimidaru
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Gynecologist's office
**Full name of responsible person**
Zeinab Rabee
**Street address**
Benafsheh Street, Kangan
**City**
Kangan

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
**Full name of responsible person**
Mostafa Feghhi
**Street address**
Golestan street, Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
**City**
Ahvaze
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
**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**
Ahvaz Jundishapur University of Medical Sciences
**Full name of responsible person**
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**Position**
Master student
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## Person responsible for scientific inquiries

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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*