

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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 configured 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 Fegghi

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

Zeinab Rabee

Position

Master student

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