

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of lactobacillus and metronidazole vaginal suppository compared with metronidazole alone on improvement and recurrence of bacterial vaginosis

Protocol summary

Summary

A clinical trial study is to compare the effect of lactobacilli and metronidazole with metronidazole alone on the recovery and recurrence of bacterial vaginitis. This is a randomized, blinded, placebo-controlled, multi-stage study, which is performed on two groups of 65 women with bacterial vaginitis at the Imam Khomeini hospital of Ahvaz. The primary inclusion criteria are: married women (15-45 years old); exclusion criteria are: pregnancy, having other infections, and so on. In this study, after obtaining permission and get a referral from the Nursing and midwifery school of Medicine and Ahvaz Imam Khomeini hospital, 130 married women 15-45 years old, who complained of a smelly discharge, vaginal or genital irritation symptoms, entered the study in order to diagnose bacterial vaginitis based on clinical Amsel criteria. After informed consent of the patients was obtained, they are divided into two groups, and two lactobacillus vaginal suppositories daily along with oral metronidazole 500 mg twice a day for a week is given to a group and controls for a week once the two numbers together with the placebo day suppositories 500 mg metronidazole orally. Slides in the laboratory are interpreted by a laboratory technician and the checklist was completed. After a week of treatment, and 4 weeks later to improve relapse are reviewed and analyzed.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2013071914057N1**

Registration date: **2014-03-08, 1392/12/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-08, 1392/12/17

Registrant information

Name

Soror Roozafzay

Name of organization / entity

Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 4322 1114

Email address

roozafzay.s@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-06-20, 1392/03/30

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lactobacillus and metronidazole vaginal suppository compared with metronidazole alone on improvement and recurrence of bacterial vaginosis

Public title

Effect of lactobacillus and metronidazole vaginal suppository compared with metronidazole alone on

improvement and recurrence of bacterial vaginosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age 15 to 45; married women; no underlying disease
Exclusion criteria: Pregnancy; Having other infections; antibiotics in the last 6 months

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

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the research deputy of Ahvaz
University of Medical Sciences

Street address

Ahvaz, Expressway, Golestan University of Medical
Sciences, Ahvaz,

City

Ahvaz

Postal code

6135715794

Approval date

2013-06-08, 1392/03/18

Ethics committee reference number

Ajumf.iec.1392.57

Health conditions studied

1

Description of health condition studied

bacterial vaginosis

ICD-10 code

1

ICD-10 code description

Bacterial infection, unspecified

Primary outcomes

1

Description

Diagnosis of Bacterial Vaginosis

Timepoint

Before treatment, one month after the treatment

Method of measurement

Based on Amsel criteria , PH Measurement Kit Merck,
Germany

Secondary outcomes

1

Description

Measurement of Vaginal discharge

Timepoint

Before treatment, one month after the treatment

Method of measurement

Amsel criteria , PH Measurement Kit Merck, Germany

Intervention groups

1

Description

The group 1 receives oral metronidazole with
Lactobacillus vaginal suppositories

Category

Treatment - Drugs

2

Description

Group 2 receives metronidazole and placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital, Ahvaz, Azadegan
Street

Full name of responsible person

Research Council of Medical Sciences, Ahvaz,

Street address

Ahvaz Imam Khomeini Hospital, Ahvaz, Azadegan
Street

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Department of Medicine, Ahwaz University users

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz

City

Ahvaz

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz Jundishapur 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**

School of Nursing and Midwifery, Medical Sciences, Ahvaz,

Full name of responsible person

khadijeh Hekmat

Position

Nursing graduate/ faculty member

Other areas of specialty/work**Street address**

Ahvaz School of Nursing and Midwifery

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-

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ahvaz Jundishapur of Medical Sciences

Full name of responsible person

khadejeh Hekmat

Position

Master of Midwifery

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Full name of responsible person

Soror Roozafzay

Position

Graduate Student Midwives

Other areas of specialty/work**Street address**

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Web page address

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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