

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The comparison of metronidazole and the combination of metronidazole and probiotic on treatment of bacterial vaginosis

Protocol summary

Summary

This clinical trial was held on 80 women, referred to Shshid Beheshti University 's Gynecology clinics, in 1389. Data collecting tools included: the Questionnaire concerning demographic profile, check list of observations for the first and second referral, microscope, and pH indicator paper. Bacterial vaginosis was diagnosed through Amsel criteria (excessive discharge, Amine test, key cells in wet setting and $\text{pH} > 4/5$). Patients were divided randomly in these two groups: " oral Metronidazole" or "combination of Metronidazole and Probiotic". Amsel criteria and patients complaints was recorded 3 and 7 days after the completion of treatment. Treatment success was considered as absence of 4 Amsel criteria or presence of one of the Amsel criteria. In this study data was analyzed with descriptive Statistics (mean and standard deviation), and inferential statistics (T test, chi-square test, Fisher's exact test, and McNemar's test), using SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106156807N1**

Registration date: **2012-05-21, 1391/03/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-21, 1391/03/01

Registrant information

Name

Sedigheh Amir Ali Akbari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2272 9240

Email address

akbarisedd@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Science & Health Service

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of metronidazole and the combination of metronidazole and probiotic on treatment of bacterial vaginosis

Public title

The comparison of metronidazole and the combination of metronidazole and probiotic on treatment of bacterial vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:1- bacterial vaginosis approval based on Amsel's criterias 2-married women aged 18-45 years 3- having one partner 4-absence of pregnancy and breast feeding 5-absence of menstruation at the time of attendance 6-not using vaginal drug, antibiotics and

immunosuppressive drugs since 14 days before starting the research 7-not having intercourse or using vaginal douche within the last 24 hours 8-absence of other types of candidias and trichomonas vaginitis at the time of study 9-not using alcohol , anticoagulant like comadin and disulfiram 10-absence of any diagnose medical disease such as diabetis , blood dyscrasia , thyroid disorders and liver disease by asking a patient 11-not using IUD. Exclusion criteria: 1-drug intolerance 2-pregnancy during therapy 3-compulsion to use antibiotics

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshty Medical University

Street address

Next to Taleghani hospital .Evin street.Tehran

City

Tehran

Postal code

Approval date

2010-12-27, 1389/10/06

Ethics committee reference number

89-01-108-7060-4467

Health conditions studied

1

Description of health condition studied

Bacterial Vaginosis

ICD-10 code

N76.7

ICD-10 code description

Other specified inflammation of vagina and vulva

Primary outcomes

1

Description

Bacterial Vaginosis

Timepoint

Before treatment and after treatment

Method of measurement

Observation

Secondary outcomes

1

Description

Bacterial Vaginosis treatment

Timepoint

3-7 days after treatment

Method of measurement

Observation

Intervention groups

1

Description

Protexin capsules manufactured by probiotics international limited, that contain lactobacillus casei, lactobacillus rhamnosus, Streptococcus thermophilus, lactobacillus acidophilus, Bifidobacterium breve, lactobacillus bulgaricus, Vitamin A, Vitamin C, Vitamin E, should be used 2 capsules daily orally for 10 days. 200 million CFU/daily Metronidazole is the drug of imidazole derivatives. In this study, oral tablets of 250 mg, 4 times daily for 7 days is given

Category

Treatment - Drugs

2

Description

Metronidazole is the drug of imidazole derivatives. In this study, oral tablets of 250 mg, 4 times daily for 7 days is given

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center on Dependent Shahid Beheshty Medical University

Full name of responsible person

Sedigheh Amir Ali Akbari

Street address

Nursing and Midwifery University, Near to Niayesh
ST, Vali-Asr Ave

City

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Email

asa_akbari@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

The Shahid Beheshti University of Medical Science &
Health Service

Full name of responsible person

Dr Masomeh Simbar

Street address

Nursing and Midwifery University, Near to Niayesh
ST, Vali-Asr Ave

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The Shahid Beheshti University of Medical Science &
Health Service

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 Shahid Beheshti University of Medical Science &
Health Service

Full name of responsible person

Sedigheh Amir Ali Akbari

Position

Master of midwifery

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

Nursing and Midwifery University, Near to Niayesh
ST, Vali-Asr Ave

City**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti Medical University

Full name of responsible person

Sedigheh Amir Ali Akbari

Position

MSM degree in midwifery education

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

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City

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Person responsible for updating data**Contact****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