Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Public title

The comparison of metronidazole and the combination of metronidazole and probitic 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 mensturation at the time of attendance 6-not using vaginal drug, antibiotics and

immonosupressive 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 trichmonas vaginitis at the time of study 9-not using alchohol , 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 intolerancy 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
Bactetial Vaginosis

ICD-10 code
N76.7

ICD-10 code description
Other specified inflammation of vagina and vulva

Primary outcomes

1

Description
Bactetial Vaginosis

Timepoint
Before treatment and after treatment

Method of measurement
Observation

Secondary outcomes

1

Description
Bactetial 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 acidodophilus,Bifidobacterium breve, lactobacillus bulgaricus, Vitamin A, Vitamin C,Vitamin E,should be used 2 capsules daily orallY for10 days.200milion 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
Tehran

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
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Person responsible for scientific inquiries

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Position
MSM degree in midwifery education
Other areas of specialty/work
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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