

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparing the therapeutic effect of oral metronidazole alone and oral metronidazole in combination with Prangos ferulacea vaginal cream on bacterial vaginosis cure.

Protocol summary

Summary

The aim of this study is to compare the effect of Therapeutic Prangos vaginal cream in combination with oral metronidazole and oral metronidazole alone in bacterial vaginosis cure. This study is a double-blind, placebo-controlled randomized clinical trial. Totally, 110 married 15-49 old women; non pregnant; non breast-feeding who complain about gray malodor discharge are treated free of charge in clinics affiliated to Khoramabad University of Medical Sciences. Diagnosis is made by three out of four Amsel criteria and Nugent criteria. Patients are divided randomly in two fifty-five person groups. We put the letter "A" or "B" on that match with the code of each regimen (The researcher know nothing about the contents of these two boxes. Then the patients take a card out of box randomly and will be given medical treatment based on the letters on the cards. Both groups will be put under treatment with oral metronidazole (Two-250 mg tablets two times a day for seven days should be taken). In addition, patients' in the intervention group are given Prangos vaginal cream and the control group are given placebo vaginal cream for seven nights. Patients who don't use the medicine at least for two days; having intercourse with partner and having no tolerance to any forms of medicine will be excluded of this research. Seven days after completing the treatment, the Amsel and Nugent criteria and side effects of medicine will be recorded. The main outcome measure is bacterial vaginosis infection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042327534N1**

Registration date: **2016-10-29, 1395/08/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-29, 1395/08/08

Registrant information

Name

Asieh Azadpourmotlagh

Name of organization / entity

(International Branch), Faculty of Nursing & Midwifery, Shahid Beheshti University of Medical Scienc

Country

Iran (Islamic Republic of)

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+98 21 8820 9020

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences.

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the therapeutic effect of oral metronidazole alone and oral metronidazole in combination with Prangos ferulacea vaginal cream on bacterial vaginosis

cure.

Public title

The effect of Prangos ferulacea vaginal cream on the treatment of bacterial vaginosis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 15-49 year old married women; non pregnant; Not breast feeding; Non menopausal; Non smoker; Willing to participate in the research; Complaine of malodor gray discharge; Not having vaginal infections; Not having unusual vaginal bleeding during the treatment; Not intercouring during the treatment; Not using vaginal ointment, suppository or douching from two days before during the treatment; Not having chronic diseases like heart or kidney problemes, diabetes, arthoritis,...; Not having any transplant; Not using broad-spectrum antibiotics, hormones, anticoagulant and immunosuppressive medicine; Not having STD disease and not being allergic to metronidazole or topical medications. Exclusion criteria: Unwilling to continue participating in the reseach; Not using vaginal ointment for two consecutive days; Being allergic to metronidazole or Prangos ferulacea vaginal cream or intolerance to any forms of medicine; having intercourse during in the treatment; Having vaginal infections (trichomonas and candidiasis with bacterial vaginosis); become pregnant during treatment; incomplete questionnaire.

Age

From **15 years** old to **49 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

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences.

Street address

No. 19, next to the Hemat bridge, Shaheed Abbaspour avenue (Tavanir), Vali Asr street.

City

Tehran

Postal code

7413934358

Approval date

2016-01-17, 1394/10/27

Ethics committee reference number

IR.SBMU.IASB.REC

Health conditions studied

1

Description of health condition studied

Bacterial vaginosis infection.

ICD-10 code

N77

ICD-10 code description

Vulvovaginal ulceration and inflammation in diseases classified elsewhere

Primary outcomes

1

Description

Studing the secretion of vaginal regarding to its color, odour and the existence of cluecells with Amsel criteria

Timepoint

Before interference and 7 days after treatment

Method of measurement

Amsel test includes 4 criteria. The existence of at least 3 criteria out of 4 to diagnose bacterial vaginosis is essential. Criteria includes homogen secretion, thin and white looks more like gray, the existence of cluecell in microscope, increasing pH vaginal to more than 4.5 and positive wiff test.

2

Description

Studing vaginal secretion with Nugent scoring.

Timepoint

Before treatment and 7 days after treatment.

Method of measurement

Nugent scoring is used to evaluate colored smear. If in vaginal disgharges, undera microscope(whit magnify 100X) the clue cell, gram negative cocobacili or mobilonococs is observed, bacterial vaginosis is diagnosed(Nugent score is more than 4).

Secondary outcomes

1

Description

Bacterial Vaginosis infection.

Timepoint

Before the intervention, seven days after start treatment.

Method of measurement

Clinical symptoms questionnaire is completed by patients (Itching, burning, abnormal discharge, malodor discharge).

Intervention groups**1****Description**

Intervention group: metronidazole 250 mg orally, 500 mg twice daily (every 12 hours) with food for 7 days in combination with Prangos vaginal cream for 7 nights

Category

Treatment - Drugs

2**Description**

Control group: metronidazole 250 mg orally, 500 mg twice daily (every 12 hours) with food for 7 days with our plasebo vaginal cream.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health centers affiliated to Lorestan University of Medical Sciences(Khorramabad city).

Full name of responsible person

Master of Midwifery student, Asieh Azadpourmotlagh

Street address**City**

Khoramabad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of Research, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences.

Full name of responsible person

Dr. Mahrokh Dolatian.

Street address

Faculty of Nursing & Midwifery, In front of Shahid Rajai Hospital, Niayesh Expressway, Valiasr St, District3, Tehran.

City

Tehran

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

Yes

Title of funding source

Deputy of Research, School of Nursing and Midwifery, Shahid Beheshti 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**

(International Branch),Shahid Beheshti University of Medical Sciences.

Full name of responsible person

Asieh Azadpourmotlagh

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Master of Midwifery student.

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City

Tehran

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