Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment effect of suppository of a drug based on Percian medicine on bacterial vaginosis

Protocol summary

Summary

This study is a randomized double-blind clinical trial. The goal of this study is a comparison of vaginal suppositories a drug based on Persian medicine (from Myrtus commuis, Foeniculum vulgare, Tamarindus indica & Tribulus terrestris) with Metronidazole vaginal suppository for treatment of bacterial vaginosis. In this study, 120 women 18-50 years refer to the Women's Hospital in Tehran (Moheb yas Hospital) with symptom of infection in genital tract that Amsel criteria for bacterial vaginosis are positive in them; after Consent, Medical history and Notification will be completed. These persons will be evaluated from uterine discharge medicine, the itching, color and odor of discharge, dilution and concentration Discharge, dyspareunia, dysuria will be checked by the PhD student. If a person suffers from other diseases, she will be excluded. Then, All patients were randomly divided into two groups, one group of people will be received based pharmaceutical products of traditional medicine and other group will be received metronidazole vaginal suppository For 7 days. It should be noted that the physician and the patient does not notice any information on the content of drugs. Two groups randomly receive coded medical kits (without drug name tag) in the form of suppositories . The next visit, a few days after the check out medication; again, tests will be done and a specialist physician will visit patients. Finally, with the help of statistical analysis evaluated the effectiveness of products compared with metronidazole vaginal Suppository.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062528613N1**
Registration date: **2016-10-22, 1395/08/01**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-10-22, 1395/08/01

Registrant information

Name

Nasrin Baery

Name of organization / entity

School of traditional medicine Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tehran University of Medical Sciences, Iranian Traditional Medicine college, Numbering Plan 25511-86-03-93

Expected recruitment start date

2016-06-07, 1395/03/18

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment effect of suppository of a drug based on Percian medicine on bacterial vaginosis

Public title

Assessment effect of suppository of a drug based on

Percian medicine on bacterial vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Outpatient women aged 18- 50 years with symptoms such as burning and itching refer and amsel criteria for bacterial vaginosis is positive for them; that Both treatments (chemical or herbal) do not use;They do not suffer from organic diseases such as cancer or other malignancies of the uterus or ovaries or Patients with chronic diseases. Exclusion criteria: Patients who use other antibiotics during the study; Patients who are experiencing possible side effect; Patients who have other medical interventions needed;This group of patients who have a severe form of the disease and other therapies and may require hospitalization have been included; Patients who request personal decision to withdraw from the study; Patients with immunosuppressive disorders; people with HIV; Patients with other infections such as genital herpes or trichomoniasis or fungal or gonorrhea at the same time with bacterial vaginosis; People who take other medication Such as the use of immunosuppressive drug or consumers of anti-inflammatory;consumers of showers vaginal and vaginal acidifying agents

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences,Qods St, Keshavarz Blvd Tehran Tehran Iran, Islamic Republic Of

City

Tehran

Postal code

Approval date

2016-06-07, 1395/03/18

Ethics committee reference number

IR.TUMS.REC.1395.2662

Health conditions studied

1

Description of health condition studied

bacterial vaginosis

ICD-10 code

N76.0

ICD-10 code description

Acute vaginitisinitis

Primary outcomes

1

Description

Amsel criteria

Timepoint

Before the intervention,10-14 days after begining of treatment

Method of measurement

Amsel have 4 criteria: key cells in the wet mount vaginal sample Vaginal dyscharge thin and white uniform - gray, white or yellowish, Vaginal pH equal to or greater than 4/5, positive whiff test. If at least 3 of the 4 cases mentioned above is positive, bacterial vaginosis is brought on .

2

Description

Clinical signs for example Malodorous discharge, Itching, dyspareunia, having bad smell during sexual intercourse

Timepoint

Before the intervention, 10-14 day after intervention

Method of measurement

Measured by asking from patient

Secondary outcomes

1

Description

Side effects

Timepoint

Within 10 to 14 days of intervention

Method of measurement

questionnaire

Intervention groups

1

Description
Consumption of vaginal Suppository from medicinal products of iranian traditional medicine based on Tribulus terrestris
Category
Treatment - Drugs

2

Description
Vaginal metronidazole suppository 500 mg for 7 nights
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Moheb Yas Hospital
Full name of responsible person
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Street address
Vali Asr Square, on the corner of Sarv & North Nejatolahi Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Dr Gholamreza Amin
Street address
School of Pharmacy Tehran University of Medical Science
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Tehran
Grant name
93-03-86-25511 طرح شماره
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Science
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

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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