

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+98 51 3855 2189

###### Email address

baeerin891@mums.ac.ir

##### 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 beginning of treatment

#### Method of measurement

Amsel have 4 criteria: key cells in the wet mount vaginal sample Vaginal discharge 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

Nasrin Baery

#### Street address

Vali Asr Square, on the corner of Sarv & North Nejatolahi Street

#### City

Tehran

## 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

#### City

Tehran

#### Grant name

طرح شماره 93-03-86-25511

#### 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

### Contact

#### Name of organization / entity

Faculty of Traditional Medicine

#### Full name of responsible person

Nasrin Baery

#### Position

Physician, PHD student

#### Other areas of specialty/work

#### Street address

Bahar St. Jihad St. front of Mehran stadium

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+98 51 3855 2189

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n.baery76@yahoo.com baererin891@mums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

School of Pharmacy Tehran University of Medical Science

#### Full name of responsible person

Dr Gholamreza Amin

#### Position

Pharmacognosy

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#### Street address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Faculty of Traditional Medicine

#### Full name of responsible person

Nasrin Baery

#### Position

PhD student of Traditional Medicin

#### Other areas of specialty/work

#### Street address

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**City**

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**Email**

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**Web page address**

**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*