

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of traditional medicine product and metronidazole vaginal gel in the treatment and prevention of recurrence in patients with bacterial vaginosis

#### Protocol summary

##### Study aim

Comparison of the effectiveness of traditional medicine product and metronidazole vaginal gel in the treatment and prevention of recurrence in patients with bacterial vaginosis

##### Design

The two-group clinical trial, with a control group, with parallel groups, triple blind, randomized, phase 2 with 60 patients. Randomization.com is used for randomization.

##### Settings and conduct

In this study, 60 women aged 18-50 years referred to gynecological clinics affiliated to Mashhad University of Medical Sciences, which were approved according to the criteria of bacterial vaginosis. The study is three-blind. Capsules and tubes of the same shape are placed in the same number in similarly numbered envelopes and therefore participants, researchers, data analysts are unaware of the intervention and control groups. Only the sample allocator to the groups is aware of the control and intervention group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Married non-pregnant and non-lactating women; 15 -44 Years old; Positive at least 3 out of 4 Amsel criteria. Non-inclusion criteria: Use of antibiotics in the last 4 weeks; Known chronic diseases; Taking coumarin anticoagulants; Diarrhea

##### Intervention groups

Intervention group: 10% rhubarb Vaginal Gel and Oral Capsule containing 200 mg of rhubarb Extract for a week. Control group: Metronidazole 0.75 mg Vaginal gel and placebo capsule for a week

##### Main outcome variables

Vaginal discharge; Vaginal acidity; Whiff test; Clue cells

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200926048840N1**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

##### Registration date

2021-09-29, 1400/07/07

##### Registrant information

##### Name

sedighe mousaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3884 8931

##### Email address

mousaeis941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-12, 1400/07/20

##### Expected recruitment end date

2021-12-23, 1400/10/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effectiveness of traditional medicine

product and metronidazole vaginal gel in the treatment and prevention of recurrence in patients with bacterial vaginosis

**Public title**

Effect of Persian medicine product on the recovery and relapse of bacterial vaginosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Married women 18 -50 years old Positive at least 3 out of 4 Amsel criteria

**Exclusion criteria:**

Pregnancy Lactation Menopause Vaginal bleeding Use of antibiotics in the last 4 weeks Known chronic diseases Using oral contraceptives to prevent pregnancy Smoking and Consuming alcohol Using Coumarin anticoagulants Multiple sexual partners Diarrhea

**Age**

From **18 years** old to **55 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We prepare 60 envelopes and numbers from one to 60. We prepare and print random numbers with the help of the Randomize.com site and put them inside the envelopes. Capsules and tubes with the same shape and same number are put in the same envelopes based on a random allocation list by a person outside the research project. We ask patients to choose an envelope containing a number and to receive the relevant medicine envelope according to the number

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The capsules and tubes in the same shape and number are placed in numbered envelopes and therefore participants, researchers and data analysts are unaware of the intervention and control groups. Only the sample allocator to the groups is aware of the control and intervention group

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Mashhad University Of Medical Sciences, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

13944-91388

**Approval date**

2020-09-12, 1399/06/22

**Ethics committee reference number**

IR.MUMS.REC.1399.429

**Health conditions studied****1****Description of health condition studied**

Bacterial vaginosis

**ICD-10 code**

Acute vagi

**ICD-10 code description**

N76.0

**Primary outcomes****1****Description**

Cure (Elimination of all Amsel criteria or remaining only one criterion and according to the agent scoring system, a score of 1 to 3 or 4 to 6 without key cells)

**Timepoint**

10 days after the start of treatment and 30 days after the end of treatment

**Method of measurement**

Amsel and Najnat criteria

**Secondary outcomes****1****Description**

Vaginal discharge

**Timepoint**

10 days after the start of treatment and 30 days after the end of treatment

**Method of measurement**

observation

## 2

### **Description**

Vaginal acidity

### **Timepoint**

10 days after the start of treatment and 30 days after the end of treatment

### **Method of measurement**

Ph strip

## 3

### **Description**

Whiff test

### **Timepoint**

10 days after the start of treatment and 30 days after the end of treatment

### **Method of measurement**

Koh 10% solution

## 4

### **Description**

Clue cells

### **Timepoint**

10 days after the start of treatment and 30 days after the end of treatment

### **Method of measurement**

Evaluation of clue cells in the wet lam

## 5

### **Description**

Nagnet score

### **Timepoint**

10 days after the start of treatment and 30 days after the end of treatment

### **Method of measurement**

Evaluation of stained slide

## **Intervention groups**

### 1

#### **Description**

Intervention group: 10% vaginal gel prepared from aqueous extract of rhubarb root and oral capsule containing 200 mg of aqueous extract of rhubarb root will be used for a week to treat bacterial vaginosis.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Vaginal gel 0.75% metronidazole and placebo capsules will be used by the samples for a week to treat bacterial vaginosis

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Emam Reza hospital

##### **Full name of responsible person**

Malihe Afiat

##### **Street address**

Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9137913316

##### **Phone**

+98 51 3802 2609

##### **Email**

afiatm@mums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Mashhad University of Medical Sciences

##### **Full name of responsible person**

Mohsen Tafaghodi

##### **Street address**

Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences, Qureshi Building, Daneshgah Ave

##### **City**

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##### **Province**

Razavi Khorasan

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13944-91388

##### **Phone**

+98 51 3841 2081

##### **Email**

vcresearch@mums.ac.ir

##### **Web page address**

<http://v-research.mums.ac.ir>

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Mashhad University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

*empty*

**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Sedigheh Moosaei  
**Position**  
PhD candidate in Iranian Traditional and Complementary Medicine  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Malihe Motavasselian  
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Associate professor  
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**Province**  
Razavi Khorasan  
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**Phone**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Sedighe Mousaei  
**Position**  
Persian Traditional Medicine Student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Traditional Medicine  
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Mashhad Faculty of Iranian and Complementary Medicine, East Door, University Campus, Azadi Square  
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mousaeis941@mums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available