

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparison of the effect of Violet plant vaginal gel and metronidazole vaginal gel in treatment of bacterial vaginosis in women of reproductive age

#### Protocol summary

##### Study aim

Comparison of the effect of Violet plant vaginal gel and metronidazole vaginal gel in treatment of bacterial vaginosis in women of reproductive age

##### Design

Randomized control clinical Trial

##### Settings and conduct

The Formulation of the vaginal Viola gel prepared in Ahvaz Jundishapur laboratory of Pharmacy School. The metronidazole vaginal gel produced by Behvazan Pharmaceutical Company, Iran. It re-filled in tubes that were similar to vaginal Viola gel tubes. The participants will randomly allocated into two groups using permuted block method with block sizes of 4 and allocation ration of 1:1 after obtaining an informed written consent. Allocation sequence will identified using computerized random numbers by a person will not involve in recruitment, data collection and analysis. All participants got two 50-gram tubes of vaginal gels to use for 7 day. The primary outcomes will be success rate on Day 7 to 10 (the positive of one or none of Amsel's criteria) and the recurrence rate (positive of at least two out of four Amsel criteria) on days 28 to 30 after starting treatment.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: Married non-pregnant and non-lactating women 15 -44 Years old, diagnosis of bacterial vaginosis based on at least 3 out of 4 Amsel criteria and gain score 4 to 6 with clue cells or score of 7 to 10 without the presence of clue cells from the Nugent scoring system and have willing to participate to study.

##### Intervention groups

the group receiving the violet plant vaginal gel

##### Main outcome variables

Vaginal discharge, Vaginal acidity, Whiff test, Clue cells

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200129046301N1**

Registration date: **2020-09-14, 1399/06/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-09-14, 1399/06/24**

Update count: **0**

##### Registration date

2020-09-14, 1399/06/24

##### Registrant information

##### Name

Parisa Afsharniya

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8837 8893

##### Email address

afsharnia.p@ajums .ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-17, 1399/01/29

##### Expected recruitment end date

2020-09-21, 1399/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison of the effect of Violet plant vaginal gel and metronidazole vaginal gel in treatment of bacterial vaginosis in women of reproductive age

**Public title**

Comparison of the Violet plant vaginal gel and metronidazole vaginal gel in treatment of bacterial vaginosis

**Purpose**

Treatment

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

The criteria for entering the study: Married non-pregnant and non-lactating women 15 -44 Years old, diagnosis of bacterial vaginosis based on at least 3 out of 4 Amsel criteria and score 4 to 6 with clue cells or a score of 7 to 10 without the presence of clue cells from the Nugent scoring system, willingness to participate to study, possibility to attending center in schedule time for post treatment follow up, Filling the Informed Consent Form.

**Exclusion criteria:**

Exclusion criteria: Vaginal bleeding, Frequently vulvovaginitis, Candidiasis, Trichomonas vaginalis, Pregnancy, Menstruation, Breastfeeding, Frequent Use of vaginal douches, Consuming alcohol and coumarin anticoagulants and recent use of anti-parasit drugs, Anti-biotic drugs, Immunosuppressive drugs, Multiple sexual partner, Specific diseases such as liver, kidney diseases and central nervous system diseases, Blood dyscrasis, Diabetes, Weakening of the immune system, Sexually transmitted diseases, History of sensitive to the forme of temperament Rocky and topical, History sensitive to metronidazol tablet.

**Age**

From **15 years** old to **44 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **88**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A total of 88 women with BV will be randomly assigned to the Violet and metronidazole groups. Randomization with random quadruple blocks, block size 4, will be done using computer software. Metronidazole and Violet labels will be encrypted as A or B by someone unaware of the purpose of the study. The formulations of Violet and metronidazole will be similar in appearance and consistency. The person who will distributed among the subjects will not be aware of the purpose of study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, is blinding allocation in such a way that the drugs will be coded by the pharmacist ( A, B) and the pharmacist will need 50gr of each type of metronidazole gel 0.75% and 50gr violet gel 5%, will be poured separately into tube of one color and shape and the taboos will be coded at the pharmacists discretion, so that only the pharmacist knows which drug A belongs to and the code B belongs to which is the drug. The research units and researcher will not have any information about the nature of the drugs until the end of the research and after analyzing the data.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committe of Ahvaz jundishapour university of medical science

**Street address**

No. 234, Golestan Blv, Ahvaz, Iran

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

1579461357

**Approval date**

2020-01-17, 1398/10/27

**Ethics committee reference number**

IR.AJUMS.REC.1398.768

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

Bacterial vaginosis

**ICD-10 code**

N76.0

**ICD-10 code description**

Acute vaginitis

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

Treatment of bacterial vaginosis

**Timepoint**

1 and 4 weeks after the intervention

### Method of measurement

According to Amsel criteria: Examination of (vaginal discharge, color, acidity, presence of clue cells, Whiff test )

## 2

### Description

Empty

### Timepoint

Empty

### Method of measurement

Empty

## Secondary outcomes

## 1

### Description

Vaginal discharge

### Timepoint

Before starting the intervention, 1 and 4 weeks after the intervention

### Method of measurement

Observation

## 2

### Description

Vaginal acidity

### Timepoint

Before starting the intervention, 1 and 4 weeks after the intervention

### Method of measurement

Ph strip

## 3

### Description

Whiff test

### Timepoint

Before starting the intervention, 1 and 4 weeks after the intervention

### Method of measurement

Koh 10%

## 4

### Description

Clue cells

### Timepoint

Before starting the intervention, 1 and 4 weeks after the intervention

### Method of measurement

Evaluation of clue cells in the wet lam

## Intervention groups

## 1

### Description

Intervention group: Vaginal gel of violet plant oil 5%, 50

mgr, made by Ahwaz School of Pharmacy 5 mg every night applicator vaginally for 7 nights.

### Category

Treatment - Drugs

## 2

### Description

Control group: Metronidazole vaginal gel 0.75%, 50 mg, made by Behvazan Pharmaceutical Company 5 mg every night with applicator vaginally for 7 nights.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Khomeini Hospital

#### Full name of responsible person

Parisa Afsharnia

#### Street address

Imam Khomeini Hospital, Azadegan Street, Ahvaz

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6193673111

#### Phone

+98 61 3222 2114

#### Email

info@ajums.ac.ir

#### Web page address

<https://himam.ajums.ac.ir/fa-IR/himam.ajums.ac/12815/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C->

## 2

### Recruitment center

#### Name of recruitment center

Health and Medical center No. 10

#### Full name of responsible person

Parisa Afsharnia

#### Street address

Main Street 3, Phase 3, Mellat Ave, East of Ahvaz

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6164873731

#### Phone

+98 61 3446 6438

#### Email

info@ajums.ac.ir

### 3

#### Recruitment center

**Name of recruitment center**

Sheiban Health and Medical center

**Full name of responsible person**

Parisa Afsharnia

**Street address**

Between 1st and 2nd streets, main boulevard,  
Sheiban

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6164873731

**Phone**

+98 61 2327 3613

**Email**

info@ajums.ac.ir

### 4

#### Recruitment center

**Name of recruitment center**

Health and Medical center No. 3

**Full name of responsible person**

Parisa Afsharnia

**Street address**

Corner of Farahani, The first of Alavi alley, End of  
Kian, West of Ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6178663141

**Phone**

+98 61 3339 2293

**Email**

info@ajums.ac.ir

### 5

#### Recruitment center

**Name of recruitment center**

Health and Medical Center No. 4

**Full name of responsible person**

Parisa Afsharnia

**Street address**

Bazaarcheh street, Saadi alley, West of Ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6194893635

**Phone**

+98 61 3334 1021

**Email**

info@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Badvi

**Street address**

Jundishapur University of Medical Sciences, Golestan  
Blv, Ahvaz

**City**

Ahavaz

**Province**

Khouzestan

**Postal code**

15794-61357

**Phone**

+98 61 3222 2114

**Email**

info@ajums.ac.ir

**Web page address**

<https://ajums.ac.ir/fa-IR/portal/1/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C#>

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Parisa Afsharnia

**Position**

Student (MSs)

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Jundishapur University of Medical Sciences, Golestan  
Blv, Ahvaz, Iran

**City**

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**Province**  
Khouzestan  
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afsharnia.p @ajums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Mina Iravani  
**Position**  
Ph.D of Reproductive Health (Midwifery)  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Jundishapur University of Medical Sciences, Golestan  
Blv, Ahvaz  
**City**  
Ahvaz  
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minairavani2004@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**

Parisa Afsharnia  
**Position**  
Student (MSs)  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Jundishapur University of Medical Sciences, Golestan  
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15794-61357  
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+98 61 3222 2114  
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afsharnia.p @ajums.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