

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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, Antibiotic drugs, Immunosuppressive drugs, Multiple sexual partner, Specific diseases such as liver, kidney diseases and central nervous system diseases, Blood dyscrasia, 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 committee of Ahvaz jundishapour university of medical science

Street address

No. 234, Golestan Blv, Ahvaz, Iran

City

Ahvaz

Province

Khuzestan

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

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Web page address

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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

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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,
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4

Recruitment center

Name of recruitment center

Health and Medical center No. 3

Full name of responsible person

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Corner of Farahani, The first of Alavi alley, End of
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5

Recruitment center

Name of recruitment center

Health and Medical Center No. 4

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Badvi

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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

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Jundishapur University of Medical Sciences, Golestan
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Person responsible for scientific inquiries

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Latest degree
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Person responsible for updating data

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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