Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 vaginl 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)

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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 frome 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 vulvovaginits, Candidiasis, Trichomonas vaginalis, Pregnancy, Mensturation, 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 untile 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

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Ahvaz

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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
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2

Recruitment center
Name of recruitment center
Health and Medical center No. 10
Full name of responsible person
Parisa Afsharnia
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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, Sheiban

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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 Kian, West of Ahvaz

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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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Bazaarcheh street, Saadi alley, West of Ahvaz

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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

Street address
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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Ph.D of Reproductive Health (Midwifery)

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Student (MSs)

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Other areas of specialty/work
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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