Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

The comparative of Poulk vaginal gel and metronidazole vaginal gel effect on treatment of bacterial vaginosis in Vaginosis patients : A Double Blind Randomized Clinical Trial

Protocol summary

Study aim

The purpose of this study is to compare the effect of poulk vaginal gel and metronidazole gel in the treatment of bacterial vaginosis.

Design

In this double-blind study there are 112 women with bacterial vaginosis who have the criteria for entering the study. They are randomly divided into intervention and control groups.

Settings and conduct

This study was carried out in clinics affiliated with Lorestan University of Medical Sciences in women with diagnosis of trichomoniasis, based on patient complaints, clinical observations and wet and colored microscopic tests. Clinical observations and wet microscopic and staining tests are reviewed within 7 days of treatment.

Participants/Inclusion and exclusion criteria

Entering criteria into the study were as fallowing : Tending to cooperate ; positive Gram stain for BV ; Positive Whiff Test ; Positive clinical observations ; Existing criteria are fallowing entries : Having abnormal uterus bleeding ; Frequently vulvovaginits ; pregnancy ; Mensturation ; Lactating ; Use of vaginal douches frequently, consuming remedy for treatment in 3 recent months ; Consumig alcohol and anti coagulation remedies and recent consuming anti-parasite remedy, anti-biotic, weakening remedy of safety system and vaginalis remedy ;Multi partner ; Stricken to specific diseases like liver diseases ,kidney diseases and central chords system diseases ,blood dyscrasi ,diabetes ,impair of safety system ; President of allergy in using metronidazol tablet

Intervention groups

Intervention group: Vaginal gel of Poulk 5%, 50 mgr, made by Ahvaz School of Pharmacy 5 mg every night applicator vaginally for 7 nights. Control group: Metronidazole vaginal gel 0.75%, 50 mg, 5 mg every night with applicator vaginally for 7 nights.

Main outcome variables

Bactrial Vaginosis ; Sexual function ; Sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201201049560N1**
Registration date: **2021-02-15, 1399/11/27**
Registration timing: **prospective**

Last update: **2021-02-15, 1399/11/27**
Update count: **0**

Registration date

2021-02-15, 1399/11/27

Registrant information

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Zohreh Shahrikh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-12, 1400/02/22

Expected recruitment end date

2021-10-06, 1400/07/14

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparative of Poulk vaginal gel and metronidazole vaginal gel effect on treatment of bacterial vaginosis in Vaginosis patients : A Double Blind Randomized Clinical Trial

Public title
The comparative of Poulk vaginal gel and metronidazole vaginal gel effect on treatment of bacterial vaginosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
willingness to cooperate positive Whiff test signs of bacterial vaginosis in examination Positive cluecell
Exclusion criteria:
Multi partner Stricken to specific diseases like liver diseases ,kidney diseases and central chords system diseases ,blood dyscrasi ,diabetes ,impair of safety system Having abnormal uterus bleeding Frequently vulvovaginits pregnancy Mensturation Lactating Use of vaginal douches frequently, consuming remedy for treatment in 3 recent months Consumig alcohol and anti coagulation remedies and recent consuming anti-parasite remedy, anti-biotic, weakening remedy of safety system and vaginalis remedy President of allergy in using metronidazol tablet consuming remedy for treatment in 3 recent months
Age
From **18 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
The allocation of individuals in the groups will be done in a random block with 19 blocks of 6 by allocation 1:1 in the two groups.In this way, the letters A and B will be assigned to each group, and randomized list provide by statistician. In this study, almost all possible cases of 19 blocks of 6 and assigning numbers to each of them are prepared randomly by a statistician using the WWW.Randomizer.org site. Poulk vaginl gel and metronidazole gel will be placed in the closed envelopes according to the randomized list and different codes by the person outside the study then assigned to any patient that enter the study. Poulk vaginal gel and metronidazole gel are identical in appearance, packaging, color.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, Researcher and participants will be unaware of the type of treatment they receive Poulk vaginal gel or metronidazole gel and pharmacist will fill the tubes. For the purpose of blinding, Poulk vaginal gel and metronidazole gel tubes will be placed in closed envelopes according to the randomized list and different codes will be assigned to any patient that enters the study by a person outside the study. Poulk vaginal gel or metronidazole gel tubes are identical in appearance, packaging and color. The patients will be reminded that their placement in each of the groups will be random.
Placebo
Not used
Assignment
Parallel
Other design features
The patients will be assigned to two groups of Poulk gel (50 g, 5%) and Metranidazole gel (50g 75%) and written consent will be obtained from patients to participate in this study. In the first group, 75% of metranidazole gel will be given daily in an intravaginal applicator daily for 7 days and in second group, 5% of poulk gel will be given daily in applicator for 7 days. Patients will be advised to stay in the supine position for at least 30 minutes after taking the drug. Patients will also be given the Larson sexual satisfaction questionnaire and FSFI sexual function questionnaire.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Ahvaz, Expressway, Golestan University of Medical Sciences, Ahvaz,
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2021-01-22, 1399/11/03
Ethics committee reference number
IR.AJUMS.REC.1399.833

Health conditions studied

1

Description of health condition studied

Bacterial Vaginosis

ICD-10 code

N76.7

ICD-10 code description

Other specified inflammation of vagina and vulva

Primary outcomes

1

Description

Bacterial Vaginosis

Timepoint

Before treatment and after treatment

Method of measurement

Based on the criteria of Amsell (Evaluation of vaginal discharge in terms of odor, color and presence of key cells with the emphasis on emphasis) and Nugent

Secondary outcomes

1

Description

Vaginal discharge

Timepoint

14-28 days after treatment

Method of measurement

Observation

2

Description

The acidity of vagina

Timepoint

14-28 days after treatment

Method of measurement

PH strip

3

Description

Whiff test

Timepoint

14-28 days after treatment

Method of measurement

Potassium hydroxide solution 10%

4

Description

clue cells

Timepoint

14-28 days after treatment

Method of measurement

Evaluation of clue cells on the wet lam

5

Description

Sexual Fanction score

Timepoint

Before and 14 days after treatment

Method of measurement

Rosen Sexual Function Questionnaire

6

Description

Sexual Satisfaction score

Timepoint

Before and 14 days after treatment

Method of measurement

Larson Sexual Satisfaction Questionnaire

Intervention groups

1

Description

5% vaginal gel, 50 g, 7 days, 1 applicator 5 g every night while sleeping inside the vagina. Extraction(Extraction of plant leaves using soaking method and using 80% aqueous solutions) and making of gel is done in school of pharmacy in Ahvaz Medical Science .

Category

Treatment - Drugs

2

Description

Control group: metronidazole vaginal gel(an applicator 75%) once a day for 7 days. Metranidazole gel made by Behsan Daroo comopany, Which is placed in tubes similar to poulk vaginal gel in school of pharmacy in Ahvaz Medical Science.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasol Clinic

Full name of responsible person

Zohreh Shahrokh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mina Iravani

Position
Associate Professor of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Position
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Midwifery

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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