Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison the effect of Sucrose gel with Metronidazole gel in the treatment of women with bacterial vaginosis

Protocol summary

Summary

This study was a double-blind randomized controlled trial. The aim of this study was to compare the ability of Sucrose and Metronidazole vaginal gel for treatment of bacterial vaginosis. In this study, 70 non-pregnant married women 15-45 years old with bacterial vaginosis were randomly assigned to two treatment groups (35 women in each group). Diagnostic criteria for bacterial vaginosis in this study was considered to be three of Amsel's criteria including: homogeneous vaginal discharge, PH of vagina ≥4.5, positive Whiff test and presence of key cells invaginal wet smear. The intervention group was prescribed Sucrose vaginal gel and the metronidazole group was prescribed Metronidazole vaginal Gel twice-a-day for 5 days. Patients were recommended to come back for follow-up 14 days after completion of treatment. In the follow-up visit, vaginal samples from all patients were taken. All results were recorded in the check lists of patients. Improvment was considered as having less than 3 Amsel's criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112631105N1**
Registration date: **2016-12-27, 1395/10/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-27, 1395/10/07

Registrant information

Name

Somayyeh Khazaeian

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology, Zahedan University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Sucrose gel with Metronidazole gel in the treatment of women with bacterial vaginosis

Public title

Comparison the effect of Sucrose gel with Metronidazole gel in the treatment of bacterial vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Married women of reproductive age (15 to 45 years old); Positive Gram staining of bacterial vaginosis; Bacterial vaginosis symptoms on clinical examination; Non-current use of anti-parasitic drugs, antibiotics, immunosuppressive drugs and vaginal medications during the past two weeks; Lack of

abnormal uterine bleeding; Not having recurrent vaginitis (4 or more than 4 times a year); No pregnancy; No breastfeeding; No use douching frequently; No alcohol and anticoagulant coumarin; No cases of multiple sex partners; No getting certain diseases, such as liver disease, diseases of the central nervous system, blood Dyscrasia, diabetes, immune deficiency; No history of allergy to mint category and garlic taken orally or topically. Exclusion criteria: Sensitivity to the drug and non-drug use; taking any prescribed medications with conflicting effect with medicines in this study; taking any drug that affect vaginosis symptoms and treatment; lack of patients interest

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committee of Zahedan University of Medical Sciences

Street address
Pardis University of Medical Sciences Campus, Hessabi Sq

City
Zahedan

Postal code

Approval date
2011-10-04, 1390/07/12

Ethics committee reference number
90-1305

Health conditions studied

1

Description of health condition studied
Bacterial vaginosis

ICD-10 code
N76.8

ICD-10 code description
Other specified inflammation of vagina and vulva

Primary outcomes

1

Description
Vaginal discharge

Timepoint
Before the intervention, two weeks after intervention

Method of measurement
Observation

2

Description
Wiff test

Timepoint
Before the intervention, two weeks after intervention

Method of measurement
Potassium hydroxide solution 10%

3

Description
Number key cells

Timepoint
Before the intervention, two weeks after intervention

Method of measurement
Gram stain

Secondary outcomes

empty

Intervention groups

1

Description
The samples used a 70-gram tube from Sucrose gel in 5 days.

Category
Treatment - Drugs

2

Description
The samples used a 70-gram tube from Metronidazole gel in 5 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital Ali Ibn Abi Talib (AS)

Full name of responsible person
Dr. Batool Teimoori

Street address
Hospital Ali Ibn Abi Talib

City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research and Technology, Zahedan University of Medical Sciences

Full name of responsible person
Dr.Mohsen Taheri

Street address
Pardis University of Medical Sciences Campus, Hessabi Sq

City
Zahedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for Research and Technology, Zahedan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
MSc

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty