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. Improvement 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

Name of organization / entity
Zahedan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Email address
somayeh.khazaiyan@sbmu.ac.ir

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 bacterial vaginosis

Public title
Comparison the effect of Sucrose gel with Metronidazole gel in the treatment of women with 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 vaginositis 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
empty

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
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
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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
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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
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
empty
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Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form