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

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)
Phone
+98 54 3323 1207
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 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
empty

Secondary Ids
empty

Ethics committees

1
Ethics committee

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

Street address
Pards 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

**City**
Zahedan

Sponsors / Funding sources

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

**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

Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Zahedan University of Medical Sciences

**Full name of responsible person**
Mahdiye Donyadari

**Position**
MSc

**Other areas of specialty/work**

**Street address**
School of Nursing and Midwifery, Mashahir Sq

**City**
Zahedan

**Postal code**
98167-43463

**Phone**
+98 54 3341 6708

**Fax**
m_khazaiyan@yahoo.com

**Email**

**Web page address**

Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Zahedan University of Medical Sciences

**Full name of responsible person**
Shahin_Dokht Navvabi Rigi

**Position**
Faculty of Midwifery / MSc

**Other areas of specialty/work**

**Street address**
School of Nursing and Midwifery, Mashahir Sq

**City**
Zahedan

**Postal code**
98167-43463

**Phone**
+98 54 3341 6708

**Fax**
shahinnavabi@yahoo.com

**Email**

**Web page address**

Person responsible for updating data

**Contact**

**Name of organization / entity**
Zahedan University of Medical Sciences

**Full name of responsible person**
Somayyeh Khazaeian

**Position**
Faculty of Midwifery / MSc

**Other areas of specialty/work**

**Street address**
School of Nursing and Midwifery, Mashahir Sq

**City**
Zahedan

**Postal code**
98167-43463

**Phone**
+98 54 3341 6708

**Fax**

**Email**
m_khazaiyan@yahoo.com

**Web page address**

Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
empty

**Study Protocol**
empty

**Statistical Analysis Plan**
empty

**Informed Consent Form**
