

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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  $\geq 4.5$ , 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

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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 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mahdiye Donyadari

**Position**

MSc

**Other areas of specialty/work**

**Street address**

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#### Person responsible for scientific inquiries

#### Contact

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#### Person responsible for updating data

#### Contact

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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*