

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of vaginal tablets of vitamin C with metronidazole on treatment of bacterial vaginosis ,clinical trials.

#### Protocol summary

##### Summary

The purpose of this study is diagnosis the effects of vitamin C vaginal tablet plus oral metronidazole on treatment of bacterial vaginosis. According to this object ,a randomized double blind control trial, 160 non-pregnant, non breastfeeding women aged between 18 to 45 years old with the randomized allocation, can be considered in a way of two groups of 80 's members. After bacterial vaginosis diagnosis by Amsel and Nagent criteria, intervention group will receive vitamin C vaginal tablet 250 mg with oral metronidazole ( prescribed with the dose of 500 mg twice a day ) during 7 days and control group will receive placebo vaginal tablet with oral metronidazole (with the same dose ). All of participants will be followed days of  $10 \pm 1$  and  $30 \pm 3$  after treatment and final diagnosis will be done according to clinical and laboratory criteria .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015042521917N3**

Registration date: **2015-05-30, 1394/03/09**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-05-30, 1394/03/09

##### Registrant information

##### Name

Sevil Hakimi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3479 6770

##### Email address

hakimis@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences. Women's Reproductive Health Research Center

##### Expected recruitment start date

2015-06-22, 1394/04/01

##### Expected recruitment end date

2015-12-22, 1394/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of vaginal tablets of vitamin C with metronidazole on treatment of bacterial vaginosis ,clinical trials.

##### Public title

Effectiveness of vaginal tablets of vitamin C with metronidazole on treatment of bacterial vaginosis. (A randomised , double blind , control trial )

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: non-pregnant and non breastfeeding married women age between 18 -45 Years Old,diagnosis of bacterial vaginosis with contemporary presence of at least three out of four Amsel criteria and gain score 4 to 6 with clue cells or score 7 to 10 without clue cells in Nugent scoring system, have willing to participate to study , possibility to attending center in schedule time for post treatment follow up , husband's monogamous ,

Filling the Informed Consent Form; Exclusion criteria: chronic disease , consumption of vaginal medication or douching during the recent weeks , Immune deficiency syndrome, consumption of antibiotic during the recent weeks , consumption of rifampin -phenytoin-phenobarbital and any anticoagulant agents , other vaginal infections ,presence of unknown vaginal bleeding

#### **Age**

From **18 years** old to **45 years** old

#### **Gender**

Female

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **160**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

Randomization with the randomized allocation

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

###### **Street address**

Faculty of Nursing & Midwifery, South Shariaty Street

###### **City**

Tabriz

###### **Postal code**

3417174914

##### **Approval date**

2015-04-13, 1394/01/24

##### **Ethics committee reference number**

TBZMED.REC.1394.5

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Bacterial Vaginosis

##### **ICD-10 code**

N70-N77

##### **ICD-10 code description**

Inflammatory diseases of female pelvic organs

### **Primary outcomes**

#### **1**

##### **Description**

Clinical and laboratory criteria based on Amsel and Nugent scoring system .

##### **Timepoint**

Before intervention,  $10 \pm 1$  and  $30 \pm 3$  days after treatment.

##### **Method of measurement**

Measured by clinical measurements of diseases and laboratory tests.

#### **2**

##### **Description**

Malodon discharge

##### **Timepoint**

Before intervention,  $10 \pm 1$  and  $30 \pm 3$  days after treatment.

##### **Method of measurement**

Measured by asking from patient

#### **3**

##### **Description**

Itching

##### **Timepoint**

Before intervention,  $10 \pm 1$  and  $30 \pm 3$  days after treatment.

##### **Method of measurement**

Measured by asking from patient

#### **4**

##### **Description**

Dyspareunia

##### **Timepoint**

Before intervention,  $10 \pm 1$  and  $30 \pm 3$  days after treatment.

##### **Method of measurement**

Measured by asking from patient

#### **5**

##### **Description**

Having fishy smell during sexual intercourse

##### **Timepoint**

Before intervention,  $10 \pm 1$  and  $30 \pm 3$  days after treatment.

##### **Method of measurement**

Measured by asking from patient

### **Secondary outcomes**

## 1

### **Description**

The vaginal PH change

### **Timepoint**

Before intervention,  $10 \pm 1$  and  $30 \pm 3$  days after treatment.

### **Method of measurement**

PH paper scale

## 2

### **Description**

Change in Clue Cells

### **Timepoint**

Before intervention,  $10 \pm 1$  and  $30 \pm 3$  days after treatment.

### **Method of measurement**

Measured by laboratory tests.

## **Intervention groups**

### 1

#### **Description**

Intervention group will receive vitamin C vaginal tablet 250 mg which produced by Faculty of Medicine Pharmaceutical group in Tabriz university of medical science with oral metronidazole ( prescribed with the dose of 500 mg twice a day ) during 7 days .

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group will receive placebo vaginal tablet along with oral metronidazole ( prescribed with the dose of 500 mg twice a day) during 7 days.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Samenol Aeme Hospital

##### **Full name of responsible person**

Toktam Dokhanchi

##### **Street address**

Imam khomeini square, Mashhad

##### **City**

Mashhad

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences. Women's Reproductive Health Research Center

#### **Full name of responsible person**

Parvin Mostafa Ghare Baghi

#### **Street address**

Alzahra Hospital, South Artesh Ave.

#### **City**

Tabriz

#### **Grant name**

-

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Tabriz University of Medical Sciences. Women's Reproductive Health Research Center

#### **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**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Sevil Hakimi

##### **Position**

PhD of reproductive health

##### **Other areas of specialty/work**

##### **Street address**

Nursing & Midwifery Faculty, South Shariati Street

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hakimis@tbzmed.ac.ir; hakimisevil@gmail.com

##### **Web page address**

## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Sevil Hakimi

##### **Position**

PhD of reproductive health

**Other areas of specialty/work****Street address**

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Tabriz University of Medical Sciences

**Full name of responsible person**

Toktam Dokhanchi

**Position**

MSc student of midwifery

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**Fax****Email**

tdokhanchi@yahoo.com

**Web page address****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*