

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The comparison of therapeutic success rate of Phytovagex vaginal suppository and oral Metronidazole on treatment of Bacterial vaginosis

Protocol summary

Summary

This research is conducted in order to follow the purpose of comparing the influence of Vaginal suppository Phytovagex with edible Metronidazole on Bacterial vaginosis , and this research will be done in the form of three random , triple-blind. These are the main criterions to be included : aged from 15 to 49, married, non-pregnant, and women coming to Mash 'had medical center number 2 complaining of smelly vaginal secretions. Diagnostic criterions are the existence of three Amsel criterions: Grey hemogen secretions -positive wiff test -PH 4.5. Eligible candi dates will be placed into two groups (A and B) randomly. 7 to 10 days after the treatment period , patients will be checked for the second time. The lack of the existence of the mentioned three Amsel criterions is considered as a successful cure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020320925N1**

Registration date: **2017-01-18, 1395/10/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-18, 1395/10/29

Registrant information

Name

Mahin Kiyani Mesk

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 8512

Email address

kianimm911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Contribute 90 percent of Credit research contract enforcement And 10 percent of funding for evidence-based research center Faculty of Nursing and Midwifery, Mashhad

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of therapeutic success rate of Phytovagex vaginal suppository and oral Metronidazole on treatment of Bacterial vaginosis

Public title

Effect of Phytovagex vaginal suppository on Bacterial vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria

(Inclusion criteria: married; the age range between 30-18 years; no pregnant; IUD is not; during breastfeeding is not; Failure to perform hysterosalpingiography , curettage and surgery of uterine in the past two weeks; absence of a history of sensitivity to oral metronidazole; broad-spectrum antibiotics and the immune system depressant drugs the past two weeks; lack of use of alcohol and

anticoagulant drugs;absence of problems and anomalies of the cervix;the absence of pelvic inflammatory disease;the Absence of abnormal uterine bleeding (AUB or DUB) Exclusion criteria: Sensitivity to prescribed drug; take antibiotics (injectable, oral or vaginal) during the intervention; not using drug more than one time)

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Doctora intersection. Ibn Sina Street

City

Mashhad

Postal code

137913199

Approval date

2015-08-01, 1394/05/10

Ethics committee reference number

IR.MUMS.REC.1394.322

Health conditions studied

1

Description of health condition studied

Bacterial Vaginosis

ICD-10 code

N77.1

ICD-10 code description

Vaginitis, vulvitis and vulvovaginitis in infectious and parasitic diseases classified elsewhere

Primary outcomes

1

Description

Amsel criteria

Timepoint

7-10 days after treatment

Method of measurement

Three Amsel criteria (homogeneous gray discharge, positive Whiff test 5.4PH $\geq$)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Phytovagex vaginal suppository, a suppository every night for seven nights

Category

Treatment - Drugs

2

Description

Control group: oral metronidazole 250 mg tablets, two tablets every 12 hours for seven nights

Category

Treatment - Drugs

3

Description

Control group:placebo suppository every night for seven nights a vaginal suppository

Category

Placebo

4

Description

Intervention group: placebo oral tablet 2 tablets every 12 hours for seven nights

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center Number2

Full name of responsible person

Farzaneh Jafarnejad

Street address

Doctora intersection. Ibn Sina Street

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen tafaghodiy

Street address

University Avenue. Central Organization of Mashhad
University of Medical Sciences

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mahin kiyani mesk

Position

Graduate Student Midwives

Other areas of specialty/work

Street address

Doctora intersection. Ibn Sina Street

City

Mashhad

Postal code

9137913199

Phone

+98 51 3852 8512

Fax

+98 51 3859 7313

Email

kianimm911@mums.ac.irmahin.kiani91@gmail.com

Web page address

http://nurse.mums.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farzaneh Jaafarnejad

Position

Master of Midwifery

Other areas of specialty/work

Street address

Doctoora intersection. Ibn Sina Street

City

Mashhad

Postal code

9137913199

Phone

+98 51 3852 8512

Fax

+98 51 3859 7313

Email

jaafarnejadf@mums.ac.ir

Web page address

http://nurse.mums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahin kiyani mesk

Position

Graduate Student Midwives

Other areas of specialty/work

Street address

Doctora intersection. Ibn Sina Street

City

Mashhad

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

+98 51 3859 7313

Email

kianimm911@mums.ac.ir

Web page address

http://nurse.mums.ac.ir/

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