

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The Comparison effects of honey vaginal gel and vaginal gel metronidazole on treatment of recurrent bacterial vaginosis

Protocol summary

Summary

This Triple-blind clinical trial was held on 61 women, referred to gynecologic clinics Tamin ejtemaie of Mashhad in 2015. Data collecting tools included: the Questionnaire concerning demographic profile, check list of amsel criteria for the first, second and third referral, and pH indicator paper, Scales and weights. Patients were divided randomly in these two groups: " honey vagina gel and Metronidazole vaginal gel. Amsel criteria and patients complaints was recorded before and 7 and 30 days after the completion of treatment. Treatment success was considered as absence of 4 Amsel criteria or presence of one of the Amsel criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012826244N1**
Registration date: **2016-07-19, 1395/04/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-19, 1395/04/29

Registrant information

Name

Negar Saki

Name of organization / entity

Medical University of Mashhad

Country

Iran (Islamic Republic of)

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+98 51 3759 3477

Email address

sakin911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison effects of honey vaginal gel and vaginal gel metronidazole on treatment of recurrent bacterial vaginosis

Public title

The comparison of honey vaginal gel with metronidazole vaginal gel on treatment of recurrent bacterial vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: proven recurrent bacterial vaginosis based on the history (of 3 or more than 3 times recurrence of symptoms and the clinical Amsel criteria; women 18-49 years old; married; single spouse; the absence of pregnancy and lactation; signed informed consent to participate in the study; not taking any vaginal medications in last 48 hours; not taking any antibiotics during the last 3 weeks; lack of vaginal intercourse or shower in the last 24 hours; no smoking; no alcohol consumption ; not taking any anticoagulants such as Coumadin and disulfiram; there is not any known medical condition like diabetes; blood Dyskrazy; thyroid disease and liver disease history; do not use IUD.
Exclusion criteria: patient's request ; the medication is

not used for more than once; no condom use during the course of treatment; Menstruation .

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 61

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences Ethics Committee

Street address

Doctora intersection, Ibn Sina Street, Mashhad

City

Mashhad

Postal code**Approval date**

2015-11-08, 1394/08/17

Ethics committee reference number

IR.MUMS.REC.1394.489

Health conditions studied**1****Description of health condition studied**

Recurrent bacterial vaginosis

ICD-10 code

N76.7

ICD-10 code description

Other specified inflammation of vagina and vulva

Primary outcomes**1****Description**

Recurrent bacterial vaginosis

Timepoint

Before treatment and after treatment

Method of measurement

Observation

Secondary outcomes**1****Description**

Recurrent bacterial vaginosis treatment

Timepoint

7 and 30 days after treatment

Method of measurement

observation

Intervention groups**1****Description**

Intervention1: Metronidazole vaginal gel in this study, 750 mg (0.75 percent) to 0.75 grams per 100 grams of metronidazole to using an applicator is recommended every night (about 5cc) before bed for 7 night

Category

Treatment - Drugs

2**Description**

Intervention 2: produced honey gel with the Iranian standards and license-mahram 30/10233.represent every night an applicator (about 5cc) applied at night before bed for seven night

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tamin Ejtemaie Gynecology Clinics of Mashhad

Full name of responsible person

Negar Saki

Street address

Kohsangi Street, Mashhad

City

Mashhad

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Vice Chancellor Of Research Mashhad University of
Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Central Organization of Mashhad University of Medical
Sciences, University Avenu, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor Of Research 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

Negar Saki

Position

Masters Student

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahin Tafazoli

Position

Master of Midwifery

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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