

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison the effect of Berberis vulgaris (in metronidazole base), Myrtus communis (in metronidazole base), and metronidazole vaginal gel alone in treatment of women with bacterial vaginosis

Protocol summary

Summary

The aim of this study was comparison the effect of Berberis vulgaris 5% in metronidazole base, Myrtus communis 2% in metronidazole base, and metronidazole 0.75% vaginal gel alone in treatment of women with bacterial vaginosis. This study was a clinical trial, double blind, single center, with random allocation. Physician and patients were unaware about the medication type. The patients were allocated randomly in the study groups according to encoded sheets. The population of study was the eligible women who referred to gynecology clinic of Hajar Hospital in Shahrekord. Inclusion criteria was diagnosis of bacterial vaginosis. The patients with sensitivity to Berberis vulgaris or Myrtus communis and treatment with systemic or topical antibiotic in the last two weeks were excluded. One hundred and twenty patients were randomly allocated in vaginal gel of Berberis vulgaris in metronidazole base, Myrtus communis in metronidazole base, or metronidazole alone groups(40 in each group). The intervention was conducted for 5 nights, with Berberis vulgaris 5% in metronidazole base, Myrtus communis 2% in metronidazole base or metronidazole vaginal gel alone. According to Amsel's criteria, the efficacy of treatment was evaluated one week later. Absence or presence of one of the Amsel's criteria was considered as primary outcome of the study. Moreover, the relapse was evaluated 3 weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411102085N13**

Registration date: **2014-12-07, 1393/09/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-07, 1393/09/16

Registrant information

Name

Neda Parvin

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1333 5652

Email address

nedali285@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord Medical University of Sciences

Expected recruitment start date

2013-08-27, 1392/06/05

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Berberis vulgaris (in metronidazole base), Myrtus communis (in metronidazole base), and metronidazole vaginal gel alone in treatment of women with bacterial vaginosis

Public title

Comparison the effect of Berberis vulgaris (in metronidazole base), Myrtus communis (in metronidazole base), and metronidazole vaginal gel alone in treatment of women with bacterial vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of bacterial vaginosis according to Amsel's criteria; married woman; age 18 to 40 years Exclusion criteria: Treatment with systemic or topical antibiotic in the last two weeks; menopause; pregnancy; hysterectomy; pelvic inflammatory disease; immune deficiency; diabetes mellitus; sensitivity to Myrtus communis or Berberis vulgaris

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

City

Shahrekord

Postal code

Approval date

2013-08-25, 1392/06/03

Ethics committee reference number

92-6-33

Health conditions studied

1

Description of health condition studied

Acute vaginitis

ICD-10 code

76.0

ICD-10 code description

Acute vaginitis

Primary outcomes

1

Description

Treatment of bacterial vaginosis

Timepoint

One week after treatment

Method of measurement

According to Amsel's criteria

Secondary outcomes

1

Description

Relapse of bacterial vaginosis

Timepoint

Three weeks after treatment

Method of measurement

According to Amsel's criteria

Intervention groups

1

Description

Myrtus communis group: The intervention was conducted for 5 nights with vaginal gel consist of Myrtus communis 2% hydroalcoholic extract in metronidazole base.
Berberis vulgaris group: The intervention was conducted for 5 nights with vaginal gel consist of Berberis vulgaris 5% hydroalcoholic extract in metronidazole base.

Category

Treatment - Drugs

2

Description

Control group: The intervention was conducted for 5 nights with metronidazole 0.75% vaginal gel alone.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology clinic of Shahrekord Hajar Hospital

Full name of responsible person

Neda Parvin

Street address

Rahmatiee, Shahrekord University of Medical Sciences, Shahrekord

City

Shahrekord

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahrekord Medical University of Sciences

Full name of responsible person

Dr Mahmood Mobasheri

Street address

Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

City

Shahrekord

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahrekord Medical University of 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**

Shahrekord University of Medical Sciences

Full name of responsible person

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Position

lecturer

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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