Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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+98 38 1333 5652
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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

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Name of organization / entity
Shahrekord University of Medical Sciences
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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